IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In re Valsartan, Losartan and Irbesartan Multi-District Litigation	)	19-md-2875 (RBK/SAK)
This document applies to all actions	)	**Opinion on TPP Trial Summary Judgment Motions**

KUGLER, United States District Court Judge

Before the Court are several related and intertwined summary judgment ["SJ"] motions under *Fed. R. Civ. Proc*. [or "*Rule*"] *56(a)* in this Multi-District Litigation ["MDL"]. These motions concern only the Valsartan portion of the MDL and precede an upcoming bellwether trial in the MDL ["the TPP trial"] among certain of the MDL parties on some of the counts in Plaintiffs' Third Amended Consolidated Economic Loss Class Action Complaint against All Defendants. Doc. No. 1708.

The parties to the TPP trial include from plaintiff's side: MSP Recovery Claims, Series, LLC ["MSP"][1] as class representative of numerous Third-Party Payors ["TPPs"], and from defendants' side: three defendants in the MDL: the Zhejiang group listed below, referred to herein as "ZHP",[2] the Teva group,[3] referred to herein as "Teva", and the Torrent group, referred to herein as "Torrent".[4] These three groups are collectively referred to herein as "defendants". As a class representative, MSP may be variously referred to herein as plaintiffs or TPPs. These SJ motions aim to reduce the claims to be presented to the fact-finder at the TPP trial.

This Opinion resolves the following Summary Judgment Motions, which Tables 1 and 2 detail:

- Doc. No. 2569[5]: Ps SJ Mot. against all Ds for Breach of Express and Implied Warranty and

[1] MSP Recovery Claims, Series, LLC is the assignee of economic loss claims from two TPP assignors SummaCare and Emblem Health.

[2] The ZHP group consists of Zhejiang Huahai Pharmaceuticals Co., Ltd, located in China and its U.S. subsidiaries: Huahai U.S. Inc.; Prinston Pharmaceutical Inc. d\b\a Solco Healthcare LLC; and Solco Healthcare U.S.

[3] The Teva group consists of Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.; Actavis LLC; and Actavis Pharma, Inc. However, regarding Teva Pharmaceuticals Ltd. ["TPL"], located in Israel, the parties have stipulated, and the Court has ordered, that for the purpose of the TPP trial, TPL is not a party. Doc. No. 2656. The terms of the parties' stipulation is discussed in the opinion *infra*.

[4] The Torrent group consists of Torrent Pharmaceuticals Ltd., located in India, and its U.S. subsidiary, Torrent Pharma, Inc.

[5] Abbreviations used throughout in this Opinion and the accompanying Order are listed in fn. 6 *infra.*

Violations of State Consumer Protection Laws and against ZHP for Fraud;
- Doc. No. 2559: Ps SJ Mot. against Torrent for Fraud;
- Doc. No.2562: Ds Omnibus SJ Mot against Ps for Not Proving Breach of Express or Implied Warranty, Violation of State Consumer Protection Laws, and Fraud);
- Doc. No.2564: ZHPs SJ Mot. against Ps for Not Proving Fraud or VCDs were Adulterated;
- Doc. No.2565: Tevas SJ Mot. against Ps for not Proving Fraud or VCDs were Adulterated; Ps have not shown Punitive Damages);
- Doc. No.2570: Torrents SJ Mot. against Ps for not Proving Fraud or VCDs were Adulterated; Ps have not shown Punitive Damages).

Table 1 summarizes plaintiffs' SJ briefs for the TPP Trial, the claims at issue, supporting submissions, defendants' oppositions, and plaintiffs' replies. Table 2 summarizes defendants' SJ briefs and submissions relating to Ds SJ Motions. As the parties' SJ motions seek opposing rulings on the same claims and issues of law, this opinion resolves all TPP Trial SJ motions.

Table 1. Plaintiffs' Summary Judgment Briefs, Defendants' Oppositions, and Ps Replies[6]

Plaintiffs as Movant					
SJ Brief Doc No.	**Against Which Ds**	**Claims**	**Supporting Doc Nos.**	**Ds Oppositions**	**Ps Replies**
2569-1: Ps SJ Brf-Omni	Teva, Torrent, ZHP	-Breach of Express & Implied Warranty; -Consumer Prot. Laws; -Violation of cGMPs in making nitrosamine-contaminated API and FD VCDs, -Which rendered the VCDs adulterated; Punitive Damages	2569-3: Ps SOMF-all Ds	2603: Ds Opp Brf 2571: D Opp SOMF	2618: Ps Rep Brf
NO individual brief filed	Teva	Ps rely on Common Law Fraud claim in 3rd Amended Complaint	2566: Ps SOMF-Teva	2602: Teva Opp SOMF	
2569-2: Ps SJ Brf-ZHP	ZHP	Common Law Fraud	2569-3: Ps SOMF-all Ds	2604: ZHP Opp Brf; 2607: ZHP Opp SOMF	
2559-1: Ps SJ Brf-TRT	Torrent	Common Law Fraud	2560: Ps SOMF-TRT	2596:Torrent Opp Brf; 2597:Torrent	

[6] The parties have sealed each SJ submission listed in Tables 1 and 2. Abbreviations in these Tables, Opinion and accompanying Order include: Defendants = Ds; Plaintiffs = Ps; Brief = Brf; Statement of Material Facts = SOMF; Opposition = Opp.; Motion = Mot.; Omnibus = Omni; state Consumer Protection Laws = CPLs; Manufacturer = mfr; Active Pharmaceutical Ingredient = API; Finished Dose = FD; Nitrosamine-contaminated Valsartan Containing Drug = VCD; Current Good Manufacturing Practices = cGMPs; Reference Listed Drug = RLD.

				OppSOMF	

Table 2. Defendants' Summary Judgment Briefs, Plaintiffs' Oppositions, and Ds Replies

Defendants as Movant					
SJ Brief Doc No.	**Movant**	**Claims**	**Supporting Doc Nos.**	**Ps Oppositions**	**Ds Replies**
2562-1: Omni SJ Brf	All Ds	Breach, Express Warranty; Breach, Implied Warranty; Common Law Fraud; State Con. Protection Laws; Ds argue: - breach of warranty unproven; - Ps cannot prove Ds proximately caused TPPs economic injury; - there is a lack of cognizable injury; - therefore Ps cannot prove fraud or warranty damages; -Ps cannot prove scienter, therefore -Ps cannot prove punitive damages		2606: Ps Opp Omni Brf 2606-2: Ps Opp SOMF	2616: Omni Rep Brf 2607: ZHP Opp SOMF to Ps Opp SOMF
2564-1: SJ Brf	ZHP	No Liability over ZHP China and Huahai: As neither entity sold VCD pills in the US, they can bear no liability; Common Law Fraud Argument: - ZHP VCDs were not adulterated; -Ps cannot prove Fraud; -Ps cannot show scienter, therefore -Ps cannot prove punitive damages		2606-1: Ps Opp ZHP Brf 2606-2: Ps Opp SOMF	2607: ZHP Reply SOMF to Ps Opp SOMF
2565-1: SJ Brf	Teva	Common Law Fraud Argument: -Teva VCDs were not adulterated; -P cannot show scienter, therefore -Ps cannot prove punitive damages	2602: Teva SOMF	2599: Ps Opp Teva Brf 2600: Ps Supp SOMF-Teva	2619: Teva Opp to Ps Supp SOMF
2570-1: SJ Brf	Torrent	Common Law Fraud Argument: - Torrent VCDs were not adulterated; and -Ps cannot show scienter,[7] therefore		2595: Ps Opp Torrent Brf	

[7] The Omnibus and Torrent SJ Briefs cite Harr*is v. Pfizer, Inc.* 586 F. Supp. 3d 231 (SDNY 2022) as instructive on whether Ds knew their product was contaminated. The Court finds *Harris* inapposite to the issue of whether the Ds or Torrent may have known the valsartan API was at risk of contamination. Ds imply that knowledge of contamination could only have arisen from FDA recalls, which brings up a completely circular argument that Ds had no duty under the FDAs cGMPs or USP compendial standards to evaluate whether the API was contaminated, and as such presumes material facts in evidence that are actually disputed. Which in turn raises a wholly circular legal argument to which the Court does not ascribe.

		-Ps cannot prove punitive damages.			

The COURT HAVING REVIEWED the parties' submissions without a hearing in accord with *Rule 78.1 (b)*, for the reasons discussed below, and for good cause shown,

1) On the claim of breach of implied warranty, the Court **GRANTS**:

defendants' Omnibus summary motion for judgment (Doc. No. 2562).

2) On the issue whether defendants' affirmations, statements, labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the Orange Book formulation, the Court **GRANTS**:

plaintiffs' Omnibus motion for summary judgment (Doc. 2569);

and **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. 2562).

3) On the issue whether the VCDs sold before the recalls began in July 2018 were adulterated, the Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569);

defendants' Omnibus summary motion for judgment (Doc. No. 2562);

ZHP's, Teva's, and Torrent's individual motions for summary judgment (Docs. No. 2564, 2565, and 2570, respectively).

4) On the issue whether defendants violated cGMPs and compendial standards in making nitrosamine-contaminated API and FD VCDs and in marketing and selling them before the recalls began in July 2018, the Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569); and

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

5) On the issue whether defendants breached express warranties to plaintiffs in TPL Express Warranty Subclass b, the Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569); and

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

6) On the issue whether plaintiffs gave defendants pre-suit notice of the breach of express warranty claim, the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562);
and **GRANTS**:
plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569).

7) On the issue whether the statute of limitations limits the filing of breach of express warranty claims in some jurisdictions in TPP Express Warranty Subclass b,
the Court **DENIES**:
Ds Omnibus motion for summary judgment (Doc. No. 2562):
and **GRANTS**:
Ps motion for summary judgment (Doc. 2569).

8) On the issue whether tolling of the statute of limitations for the express warranty claim may be justified in some or all jurisdictions in the TPP Express Warranty Subclass b,
the Court **DENIES**:
plaintiff's Omnibus motion for summary judgment (Doc. No. 2569); and
defendants Omnibus motion for summary judgment (Doc. No. 2562).

9) On the issue whether plaintiffs relied on defendants' express warranties, the Court **DENIES**:
plaintiff's Omnibus motion for summary judgment (Doc. No. 2569); and
defendants Omnibus motion for summary judgment (Doc. No. 2562).

10) On the issue of violation of Consumer Protection Statutes,
the Court **DENIES**:
plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569);
defendants' Omnibus motion (Doc. 2562); and
Teva's motion for summary judgment (Doc. No. 2565),
EXCEPT the Court **GRANTS:**
defendants' Omnibus motion (Doc. 2562) and Teva's motion (Doc. No. 2565) for these claims in Missouri.

11) On the issue of fraud , the Court **DENIES**:
plaintiffs' motion for summary judgment against ZHP (Doc. No. 2569); and
plaintiffs' motion for summary judgment against Torrent (Doc. No. 2559).

defendants' Omnibus motion for summary judgment (Doc. No. 2562);

defendant ZHP's motion for summary judgment (Doc. No. 2564);
defendant Teva's motion for summary judgment (Doc. No. 2565); and
defendant Torrent's motion for summary judgment (Doc. No. 2570).

12) On the damages issue whether plaintiffs have no cognizable injury,
the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

13) On the damages issue whether plaintiffs' model of damages cannot establish damages on a class-wide basis,
the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

14) On the damages issue whether plaintiffs cannot prove that defendants' alleged conduct and/or misrepresentations proximately caused plaintiffs any injury,
the Court **DENIES**:
defendants' Omnibus motion for summary judgment (Doc. No. 2562).

15) On the damages issue whether plaintiffs cannot prove fraud and breach of warranty damages,
the Court **DENIES**:
defendants' Omnibus motion for summary judgment (Doc. No. 2562).

16) On the damages issue whether plaintiffs cannot prove punitive damages,
the Court **DENIES**:
defendants' Omnibus motion for summary judgment (Doc. No. 2562),
EXCEPT
the Court **GRANTS**:

defendant's Omnibus summary judgment motion (Doc. No. 2562) on the issue that plaintiffs cannot prove punitive damages in Nebraska and New Hampshire, for breach of express warranty and for violation of Consumer Protection Laws.

An Order of this date accompanies this Opinion.

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1.0 Background Relevant to the TPP Trial

1.1 Generally

The TPP trial in this MDL concerns only the Valsartan subset of drugs, that is, a generic pharmaceutical containing generic Valsartan Active Pharmaceutical Ingredient ["API"] made by ZHP at a manufacturing facility in China and fashioned into finished-dose ["FD"] pills by ZHP and its subsidiaries listed in fn. 2, and a Torrent U.S. subsidiary as well as Teva U.S. subsidiaries, which marketing and sold the pills to consumers in the U.S.

By 5 Jun 2018, ZHP had been alerted by one of its API customers that its API was contaminated with nitrosamines.[8] By the next day ZHP notified Prinston and Solco, its U.S. subsidiaries involved in making and/or distributing generic valsartan pills, of the contamination. Simultaneously, by early July 2018, the U.S. Federal Drug Administration ["FDA"] and several of its counterparts in the European Union, Canada, Denmark, etc. discovered that certain batches of generic Valsartan[9], a quite universally prescribed drug to lower blood pressure, contained nitrosamines, identified by international medical authorities as probable genotoxic carcinogens. The first nitrosamine contaminant found was N-nitrosodimethylamine ["NDMA"]. Within a few months, another nitrosamine, N-Nitrosodimethylamine ["NDEA"] was found in batches of valsartan pills sold in the U.S. In early July 2018, the FDA also notified ZHP of the nitrosamine contamination of its API and finished dose pills.

As used herein, valsartan containing drugs contaminated with nitrosamines are referred to as **VCDs** and includes for this opinion both the nitrosamine-contaminated API as well as the finished dose pills manufactured with nitrosamine-contaminated API. The term VCDs includes all dosages of finished dose pills and the wide variety of drug formulations that comprise either primarily valsartan or a combination of valsartan with other medicaments.

Prinston began a voluntary recall of ZHPs VCDs on 17 Jul 2018. Both API and FD manufacturers ["mfrs"] involved in the TPP trial include the ZHP defendant group-the API and FD mfr located in China as well as its finished dose and distribution subsidiaries located in the U.S. ZHP sold its API to several FD mfrs located in Israel and India, which include defendants Teva and Torrent respectively, also involved in the TPP trial. The greater percentage of VCDs sold in the U.S. before FDA disclosure of the contamination had come from ZHPs

[8] To be clear, a genotoxic carcinogen is an agent that causes damage to the DNA in humans. The gene or chromosomal damage then initiates carcinogenesis by accelerating growth in the damaged cells as well as increased vascularization which promotes faster growth of the damaged cells into cancerous tissue.

[9] Valsartan is the generic name of Diovan®, a patented anti-hypertensive drug the patent for which has expired. It is also used in a combination heart failure drug called Exforge®.

contaminated API. Other API mfrs also made contaminated valsartan API and other FD mfrs put that into VCDs sold in the U.S., but those other mfrs are not involved in the TPP trial, only the ZHP, Teva, and Torrent groups.

Sartan drugs, including valsartan, were (and to a large extent remain) drugs of medical choice in lowering high blood pressure. It was estimated there were over 2 million Americans taking valsartan before the FDA disclosure in July 2015. Since VCDs were widely prescribed worldwide and in the U.S., the recalls caused consternation during much of 2019 in the global medical community, including the American Medical Association. Certainly by November 2018, the FDA (and non-U.S. medical authorities) posited the contaminants in the VCDs to be the result of changes the API Mfrs had adopted in their manufacturing processes, particularly by changing the solvents and the solvent-extracting reagents in those processes. Some API Mfrs had adopted manufacturing changes as early as 2012. However, ZHP sold its contaminated API at least from 2015 onwards. Thus, contaminated API potentially was present in much of the Valsartan drug supply sold in the U.S. from at least 2015 until the recall in July 2018.

By late August 2018, plaintiffs had begun filing personal injury individual complaints. By October 2018, third-party payors ["TPPs"], who had paid or reimbursed in whole or in part for prescriptions of VCDs, ingested by their insureds, US consumers, had filed several complaints. On 14 Feb 2019, the Judicial Panel on Multi-District Litigation ["JPML"] consolidated all of the individual filings into this MDL, No. 2875. For details of the past five years of factual and procedural background of this MDL, see the following: Doc Nos. 675, 728, 775, 818, 839, 1019, 1708, 1753, 1811, 1825, 1838, 1958, 1974,1994, 2261, 2368, 2343, 2518, 2529, 2535, 2546, 2555, and 2582.

The TPP trial concerns claims of certain certified subclasses of plaintiffs against the three mfr defendant groups for TPP economic losses in reimbursing, wholly or partly, their insureds' VCDs, sold in the U.S. from 2015 to about July 2018.

1.2 TPP Trial Plaintiffs and Their Claims

Plaintiffs include the certified subclasses of TPPs listed below for which MSP is the class representative. MSP is an assignee of the insurance claims of two Third Party Payors ["TPP"]—pharmaceutical insurers that pay for/ reimburse consumers' prescription drugs. The two TPP assignors of MSP's economic loss claims are Group Health Incorporated and Health Insurance Plan of Greater New York ["Emblem"] and SummaCare, Inc. ["Summacare"]. Plaintiff MSP is asserting it should be granted Summary Judgment under *Rule 56* on behalf of the relevant, certified subclass for each of the enumerated claims:

Breach of Express Warranty against all 3 defendants on behalf of the certified **TPP Express Warranty Subclass Group b**, which includes these jurisdictions: Alabama, Arkansas, Florida, Georgia, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin, and Wyoming;

Breach of Implied Warranty, for the certified **TPP Implied Warranty Subclass Group d** (having granted Ds SJ motion that this claim fails as a matter of law, the Court does not list the states in this subclass);

State Consumer Protection ["CPL"] Laws against all 3 defendants on behalf the of the certified **TPP Consumer Protection Laws Subclass Group a**, which includes those jurisdictions where no showing of intent is required to prove deception: Alaska, Arizona, California, Connecticut, Florida, Louisiana, Missouri, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, and Washington;[10] and

Common Law Fraud against all 3 defendants on behalf of the certified **TPP Common Law Fraud Subclass Group c**, which includes those jurisdictions where the scienter standard is the highest: Alaska, Arkansas, Colorado, District of Columbia, Florida, Idaho, Iowa, Louisiana, Massachusetts, Minnesota, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wyoming, and Puerto Rico.

1.3 TPP Trial Defendants

The TPP Trial defendants are ZHP, Torrent, and Teva as described *supra* in fns. 2,3, and 4. As stated above, these defendants either made valsartan API and/or finished it into pills. ZHP includes a Chinese API manufacturer and its wholly-owned U.S. subsidiaries that put the Chinese-made API into finished dose VCDs. Torrent includes Indian and U.S. FD mfrs that put ZHP API into their FD pills. Teva includes an Israeli parent of U.S. subsidiaries that also put ZHP API into their FD pills. All three defendants marketed, sold, and distributed their contaminated VCDs into the U.S. market.

Besides seeking summary judgment on each of these four claims for Ps failure to meet *Rule 56* requirements, Ds also seek summary judgment on several damages issues, including that Ps have no cognizable injury, which translates into a request to preclude an award of damages to TPPs. In turn, Ps argue they have viable claims for punitive damages for their

[10] Missouri, Nebraska, Oklahoma, Oregon, and Pennsylvania do not expressly look to the Federal Trade Commission Act jurisprudence to define "deception", while the rest of subclass a jurisdictions do.

common law fraud claim against all 3 Ds. All parties seek opposing motions for summary judgment that the VCDs sold into the U.S. market were or not adulterated as a matter of law.

2.0 Arguments Regarding Jurisdiction over and Liability of ZHP China and Teva Israel

Before weighing into the parties' arguments on summary judgment, as an essential first step, the Court looks to arguments that implicitly or expressly relate to this Court's jurisdiction over ZHP China or TLP (located in Israel) because as the non-US entities of the relevant group, neither sold any VCDs in the U.S. The Court notes Torrent raised no jurisdictional disputes concerning Torrent India.

2.1 ZHP

ZHP's brief in support of its supplemental motion for Summary Judgment (Doc. No. 2564-1) asserts the Chinese API manufacturer, ZHP China, did not sell VCDs in the U.S. and that its US subsidiaries were "indirect" [a term undefined in the ZHP SJ brief]. Therefore, ZHP China can have no liability for TPPs economic loss in reimbursing for the contaminated VCDs ZHP U.S. subsidiaries sold here. This argument raises an implicit, unbriefed jurisdictional dispute, in that ZHP China may argue, having conducted no direct sales, marketing or distribution in the U.S., it has insufficient contacts to any US jurisdiction, which precludes jurisdiction by a US court. Further, the Court acknowledges that ZHP has averred in its Motions for Leave to File their First and Second Amended Answer (Doc. Nos. 2628 and 2762 that they aver this Court has no jurisdiction over ZHP China.

Neither the lack of liability nor the potential lack of US Court jurisdiction argument is defensible or plausible. The Court observes that ZHP admits in its Answer to the Third Amended Complaint (Doc. No. 2549:¶¶76-78) that ZHP China has a 100% controlling interest in each U.S. subsidiary, making each a wholly-owned subsidiary.[11] The issue of ZHPs liability is resolved if the subsidiaries of ZHP are but divisions of it and lack their own genuine corporate identity.

[11] The definition of a wholly-owned subsidiary, even though deemed a separate legal entity, is that it is 100% owned and controlled by the parent, working directly under the guidance and decision-making of the parent. Moreover, even if the wholly-owned subsidiary has its own senior management that manages the subsidiary's day-to-day business operations, when the parent dominates all strategic decisions that direct the subsidiary's business, the subsidiary is deemed but an agent of the parent. ABA Publishing (2012), Corporate Counsel Guides Corporation Law, 1st Edition, Chapter 7, The Separate Corporate Entity: Privilege & Its Limitations; Piercing the Corporate Veil, pp.92-97.

Therefore, from the definition of a wholly-owned subsidiary and from the operation of that subsidiary as a vertically integrated subdivision of a foreign parent , that subsidiary's sales, marketing, and distribution of a foreign-produced product finished either in the US or elsewhere are deemed directed and controlled by the foreign parent.

Mr. Du, Jun testified as a ZHP Rule 30(b)(6) corporate representative in his deposition that, at the relevant time of the ZHP recalls in 2018, he was the Vice Chair of the Board of Directors of ZHP China, the overarching parent, AND the CEO of Huahai U.S., AND the CEO of Prinston Pharmaceuticals, AND the CEO of Solco Healthcare, all ZHP defendants here. Ps SOMF:¶¶2-3. Mr. Du also testified that "ZHP (the parent in China) sells its API products directly in the U.S. market through Huahai U.S., including both the research and development APIs, as well as commercialized APIs." *Id*.:¶6. This statement in and of itself suffices to confer jurisdiction. Nevertheless, given that ZHP wholly owned all of the subsidiaries in the ZHP defendant group in fn. 2, Mr. Du's assertion as the functional second in command of ZHP becomes important in untangling whether these subsidiaries had a separate corporate existence, that is, were agents of ZHP, or could have their corporate veil pierced because ZHP controlled not only their management but their daily operations.

Mr. Du's assertions are borne out by the testimony of another 30(b)(6) corporate representative of ZHP, Wang, Hai. Mr. Wang declared he is President of Solco Healthcare, AND Senior Vice President of Prinston Pharmaceutical, Inc., AND Senior Vice President of Huahai U.S, Inc., AND reported directly to Mr. Du in all of his positions. *Id*. at ¶4. Solco and Prinston are ZHP subsidiaries in the U.S.

Mr. Wang also testified that Prinston is the corporate body of the ZHP organization, which means Prinston acts as the corporate center. *Id*. at 8. Mr. Du explained: among other things, Prinston is the owner of the Abbreviated New Drug Applications ["ANDAs"] of generic drugs marketed and sold in the U.S., and Solco is the marketing arm of Prinston. Mr. Wang confirmed Solco is a wholly owned subsidiary of ZHP. *Id*.:¶¶6, 8.

In their Opp. SOMF, Ps assert that Chen, Baohua, CEO of ZHP and located in China, micromanaged efforts at the level of its U.S. subsidiaries to obtain greater market share for ZHPs VCDs in the U.S.[12] Ps Opp. SOMF, Doc. No. 2606-2:¶4. Contrary to assertions in Ds Omni SJ Mot., ZHP sold FD VCDs directly to Prinston (ZHP Exhs. 153 and 154) and directly flies in the face of ZHPs claim of no marketing or selling in the U.S., which precludes its liability for contaminated VCDs. Moreover, ZHPs, Huahais, Prinstons and Solcos logos all appeared on Solcos Product List (ZHP Ex. 152), thus informing the public that all products in the Solco line were from a single entity, but were only from different manufacturing or marketing lines, like different car models being sold by a single car manufacturer.

The Court has examined how the ZHP defendants represent themselves online in order

[12] ZHP Exh. 158, which shows Mr. Chen deciding what market share to target for valsartan at ZHP and the U.S. subsidiaries. Ps assert only Mr. Chen was responsible for creating market share targets. Ps Opp. SOMF:4, fn. 4.

to understand what customers and consumers see. The Court takes official notice of the Linked-In Page for Huahai US, Inc., which states "Huahai US, Inc. is a wholly owned subsidiary of Zhejiang Huahai Pharmaceutical Co. Ltd."[13] The Court also takes official notice of the Organizations page of the Prinston Pharmaceuticals website, which displays the ownership structure and wholly owned relationship among ZHP China and the other ZHP entities in this matter.[14] This Prinston Organizational page bears out what Mr. Du testified to, that Prinston is the corporate face in the U.S. of the ZHP conglomerate. The Court finds that ZHPs representations of corporate control and governance on its subsidiaries' websites and in ZHPs exhibits, especially regarding Mr. Chen's persistent, enduring control of the generic drug selling and marketing, to be admissions of the vertical integration of ZHP and its subsidiaries. To be clear, such integration and admissions depict that the subsidiaries functioned as divisions and not as corporations independent of the ZHP parent's control and governance.

From Mr. Du's testimony, from ZHPs admissions of this Court's personal jurisdiction over it, from ZHPs website descriptions and its own Exhibits describing its domination over its subsidiaries, the Court finds ZHP China controlled the marketing, sale, and distribution of its VCDs in the U.S. Because of ZHP China's control over its VCDs in the U.S., the Court finds ZHP China bears liability for the U.S. sales of FD VCDs, for which the Court has jurisdiction over ZHP China and Huahai U.S.

ZHPs arguments that it and Huahai U.S. are not liable for FD VCDs in the U.S. presents an implicit, roundabout attack on this Court's personal jurisdiction over ZHP China raised for the first time only at this summary judgment phase five years into this MDL litigation. Intending to avoid a throw-away argument raised by ZHP in its summary judgment motion from becoming elevated to a previously unforeseen but increasingly raised matter in the future of this MDL, the Court has found that many state and federal jurisdictions rely on similar theories—alter ego or agency theory—and substantially similar factors to resolve when the subsidiary is either the mere agent of the parent and dominated by it or when33 the corporate veil of a parent's non-liability can be pieced.[15] By listing the case law in fn. 15, the Court

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[13] *See* https://www.linkedin.com/company/huahai-us-inc. (last accessed 15 Feb 2024).

[14] See http://www.prinstonpharm.com/col.jsp?id=171 (last accessed 15 Feb 2024).

[15] **1ST CIRCUIT**

Barsoum v. Kinderhook Industries, LLC , Civ. No. 23-10928, 2023 WL 7413409, at *1 (D. Mass. 8 Nov 2023): Under Massachusetts law, to pierce the corporate veil, a court must conclude upon evaluating relevant factors, that the parent corporation directed and controlled the subsidiary and used it for an improper purpose, that is, to properly impute liability based on agency principles.

Hernandez–Denizac v. Kia Motors Corporation, 257 F.Supp.3d 216, 223-224 (D.P.R. 2017): there is a presumption of corporate separateness that must be overcome by clear evidence that the parent in fact controls the activities of the subsidiary. To disregard corporate form, courts conduct a highly fact-specific inquiry. The personal jurisdiction inquiry must necessarily focus on a defendant's relationship to the forum State.

2ND CIRCUIT

Soter Technologies, LLC v. IP Video Corp., 523 F.Supp.3d 389, 411 (S.D.N.Y. 2021): Alter ego liability exists where the corporation has been so dominated by a parent corporation that its separate identity is disregarded and it primarily transacted the dominator's business rather than its own.

Miami Products & Chemical Co. v. Olin Corporation, 449 F.Supp.3d 136, 181 (W.D.N.Y. 2020): An indicator of the existence of an agency relationship between a parent and its subsidiary is whether the parent would be obliged to enter the market directly if the subsidiary were absent because the market is too important to the parent's welfare. Where a subsidiary's business is dependent on the parent's business, or vice versa, an inference may often be drawn that the parent controls the subsidiary as it would a department.

3RD CIRCUIT

In re Clearview AI, Inc. Consumer Privacy Litigation, 585 F.Supp.3d 1111, 1125 (N.D. Ill. 2022): Under Delaware law, a parent corporation is held liable for the actions of its subsidiary if the parent directed or authorized those actions.

Mills v. Ethicon, Inc., 406 F.Supp.3d 363, 393 (D.N.J. 2019): Under New Jersey law, jurisdiction over a foreign parent holds only if the subsidiary is an alter ego or agent of the parent determined by these 4 factors: (1) whether the subsidiary is doing business in the forum that would otherwise be performed by the parent, (2) whether there is common ownership of the parent and subsidiary, (3) whether there is financial dependency, and (4) whether the parent interferes with the subsidiary's personnel, disregards the corporate formalities, and/or controls the subsidiary's marketing and operational policies.

Trinity Industries, Inc. v. Greenlease Holding Company, 903 F.3d 333, 367 (3rd Cir. 2018): To pierce the corporate veil under Pennsylvania law a threshold showing is required that the controlled corporation acted robot- or puppet-like in mechanical response to the controlling shareholder's demands.

In re Boltz-Rubinstein, 596 B.R. 494, 507 (E.D. Pa. 2019): Under Pennsylvania law, to obliterate the separate corporate status in the parent/subsidiary context, a plaintiff must prove that: (1) the parent exercised sufficient domination and control over the subsidiary corporation such that the subsidiary was a mere alter ego of the parent, with no separate existence, and (2) injustice will result if the corporate fiction is maintained.

4TH CIRCUIT

United States ex rel. Fadlalla v. DynCorp International LLC, 402 F.Supp.3d 162, 193 (D. Md. 2019): The inquiry is twofold. First, the Court must determine whether a unity of interest exists between the two entities sufficient to permit treatment of the two entities as one. Next, the Court considers whether doing so would produce an inequitable result. The first element looks to which formalities have been followed to maintain separate corporate identities, and the second element looks to the basic issue of fairness under the facts.

Chamberlain v. Securian Financial Group, Inc., 180 F.Supp.3d 381, 406 n. 8 (W.D.N.C. 2016): To find that a subsidiary is a mere instrumentality of the parent, North Carolina law requires a showing that the parent exercises complete domination, not only of finances, but of policy and business practice.

6TH CIRCUIT

Mattingly v. R.J. Corman Railroad Group, LLC, 90 F.4th 478, 488 (6th Cir. 2024): Under Kentucky law, two elements must be met: "(1) domination of the corporation resulting in a loss of corporate separateness *and* (2) circumstances under which continued recognition of the corporation would sanction fraud or promote injustice.

Lyngaas v. Curaden Ag et al., 992 F.3d 412, 421 (6th Cir. 2021): Under Michigan law, to pierce the corporate veil, it is unnecessary to prove that the parent caused the subsidiary to directly harm complainant; it suffices if parent exercised control over subsidiary in such a manner as to wrong plaintiff.

See also In re Flint Water Cases, 584 F.Supp.3d 383, 399 (E.D. Mich. 2022): Under Michigan law, a plaintiff may seek to pierce the corporate veil to hold the defendant parent company liable for the actions of its subsidiary and the decision of whether to consider a subsidiary as the parent's alter ego is highly dependent on the equities of the situation, and the inquiry tends to be intensively fact-driven.

7th CIRCUIT

BCBSM, Inc. v. Walgreen Co., 512 F.Supp.3d 837, (N.D. Ill. 2021): Under Illinois law as a general rule, a parent corporation may not be held to account for the liabilities of a subsidiary unless the legal separateness of parent and subsidiary has been disregarded in a wide range of corporate matters. Here, the health insurer alleged that the pharmacy company and parent corporation were so integrated that the allegedly fraudulent scheme could be attributed to both entities and the Court agreed.

8TH CIRCUIT

Hawkeye Gold, LLC v. China National Materials Industry Import and Export Corporation, 89 F.4th 1023, 1035 (8th Circ. 2023): Iowa law recognizes corporate subsidiary's separate corporate identity but under exceptional circumstances will disregard subsidiary's separate identity, i.e., pierce the corporate veil, where doing so would prevent parent from perpetuating fraud or injustice, evading just responsibility or defeating public convenience.

Sacred Heart Health Services v. MMIC Insurance, Inc., 575 F.Supp.3d 1137, 1191 (D.S.D. 2021): Under South Dakota law, the corporate veil may be pierced if two elements are met: (1) the parent controls the subsidiary in such way that renders the latter the mere instrumentality of the former, and (2) adherence to the rule of corporate separateness would produce injustices and inequities, this second prong is established where the wrong alleged is a result of fraudulent, unjust or illegal acts.

Goellner-Grant v. Platinum Equity LLC, 341 F.Supp.3d 1022, 1028-29 (E.D. Mo. 2018): Under Missouri law alter ego theory, courts hold parent companies liable for actions of the subsidiary because of their total control and their improper use of the subsidiary, and it is these aspects which cause all activities—and all liabilities—of the subsidiary to become those of the parent; in such instances, the subsidiary is simply a shell designed to artificially distance the parent company from what are, in reality, its own acts.

9TH CIRCUIT

GeoSolutions B.V. v. Sina.com Online, Civ. No. 5:21-08019, 2023 WL 2562392, at *3-5 (N.D. Cal. 27 Oct 23): Under California law, to establish an alter ego relationship between a parent and subsidiary requires a prima facie showing (1) there is such unity of interest and ownership that the separate entities no longer exist and (2) failure to disregard those separate identities would result in fraud or injustice. The unity of interest prong includes 9 factors, but the court need not find every factor, it need only conclude that one entity controls the other as to render the latter the mere instrumentality of the former.

Riot Games, Inc. v. Suga PTE, Ltd., 638 F.Supp.3d 1102 (C.D. Cal. 2022): same as *GeoSolutions*.

In re Packaged Seafood Products Antitrust Litigation, 242 F.Supp.3d 1033, 1062 (S.D. Cal. 2017): The alter ego test is satisfied where a parent corporation uses its subsidiary as a marketing conduit and attempts to shield itself from liability based on its subsidiary's activities. California courts have stated that "[t]he purpose behind the alter ego doctrine is to prevent defendants who are the alter egos of a sham corporation from escaping personal liability for its debts.

Cox v. Global Tool Supply LLC, 629 F.Supp.3d 963, 973 (D. Ariz. 2022): Under Arizona alter ego theory that (1) unity of control and (2) observance of the corporate form would sanction a fraud or promote injustice must be shown. Same factors as in GeoSolutions and In re Packaged Seafood.

10th CIRCUIT

Cyprus Amax Minerals Company v. TCI Pacific Communications, LLC, 28 F.4th 996, 1007 (10th Cir. 2022): Under Kansas law, presumption of corporate separateness is overcome only with proof of two elements: if allowing the legal fiction of separate corporate structure would result in injustice toward plaintiff, or if the subsidiary is the alter ego of its parent. Ten factors are considered to find whether the subsidiary is an alter ego, which are guidelines and not tallied but taken as a whole with due regard to the extent to which they were or not fully satisfied.

Young through Young v. Kerr-McGee Corp., 658 F.Supp.3d 1028, 1035 (E.D. Okla. 2023): Under Oklahoma law, if one corporation is simply the instrumentality of another corporation, the separation between the two may be disregarded and treated as one for the purpose of tort law. Courts considers the same 10 factors as in *Cyprus:* 1) the parent corporation owns all or most of the subsidiary's stock; 2) the corporations have common directors or officers; 3) the parent provides financing to its subsidiary; 4) the dominant corporation subscribes to all the other's stock; 5) the subordinate corporation is grossly undercapitalized; 6) the parent pays the salaries, expenses, or losses of the subsidiary; 7) almost all of the subsidiary's business is with the parent or the assets of the former were conveyed from the latter; 8) the parent refers to its subsidiary as a division or department; 9) the subsidiary's officers or directors follow directions from the parent; and 10) legal formalities for keeping the entities separate and independent are observed.

BASF Corporation v. Willowood, LLC, 359 F.Supp.3d 1018, 1025-1026 (D. Colo. 2019): In Colorado, the agency theory of personal jurisdiction is based on the concept that a principal is responsible for the actions of its agent. An agent can make his principal responsible for his actions if he is acting pursuant to either actual or apparent authority. An agent may be a corporation as well as an individual. As all corporations must necessarily act through agents, a wholly owned subsidiary may be an agent and when its activities as an agent amount to doing the business of the parent, the parent is subjected to the in personam jurisdiction of the state.

In re Santa Fe Natural Tobacco Company Marketing & Sales Practices and Products Liability Litigation, 288 F.Supp.3d 1087, 1214-1215 (D.N.M. 2017): New Mexico follows the alter ego theory in that a subsidiary is an alter ego if it is a mere instrumentality of the parent.

11th CIRCUIT

provides a sampling of state law cases regarding alter ego/parent domination or piercing the corporate veil and does not represent that these jurisdictions correspond to the states named in the relevant subclasses. Even though different Circuits and/or districts may have more strict approaches to reviewing relevant factors, the Court observes the cases cited in fn. 15 are from sufficiently diverse jurisdictions to suggest a general set of standards for showing parent dominion over a subsidiary and its liability for subsidiary conduct and/or for piercing the corporate veil for liability. Singularly prominent in all these cases is the equity factor. To wit, if the Court's decision— that the parent did not dominate the subsidiary or the subsidiary was more than the parent's agent—would work an injustice, the inequity factor weighs heavily, even clearly and convincingly, towards a finding of personal jurisdiction over a foreign actor to avoid using the U.S. subsidiary as a shield for its actions.

As the Court has taken pains to analyze the domination ZHP China exercises over its U.S. subsidiaries, equity is only one factor considered. The Court finds that ZHP China is subject to this Court's jurisdiction, and, because of ZHPs domination over its subsidiaries , ZHP has incurred its own liability for the U.S. sales of FD VCDs.

2.2 Teva

The parties have stipulated, and the Court has ordered, that Teva Pharmaceuticals Ltd. ["TPL"], located in Israel, is not a party in the TPP trial and is voluntarily dismissed without prejudice from all claims asserted by the TPP Trial Subclasses. Doc. No. 2656. The stipulation also states: it has no effect on any other MDL claims asserted against TPL; it shall not be construed to prohibit the naming of TPL as a party in MDL matters other than the TPP trial; and all parties reserve their rights concerning personal jurisdiction over TPL.

All three Teva entities in fn. 3 *supra* are parties to the TPP trial and are U.S. headquartered.[16]

Herederos De Roberto Gomez Cabrera, LLC v. Teck Resources LTD, 43 F.4th 1303, 1312 (11th Cir. 2022): There is no litmus test for determining if the subsidiary is the alter ego of its parent; instead, a court must look to totality of circumstances. Resolution of the *alter ego* issue is heavily fact-specific and peculiarly within the province of the trial court.

Alvarez Galvez v. Fanjul Corp., 533 F.Supp.3d 1268, 1283-85 (S.D. Fla. 2021): A parent company can be held liable for the acts of its subsidiaries in three ways: (1) an alter ego theory to pierce the corporate veil; (2) vicarious liability based on general agency principles; or (3) direct liability where the parent directly participated in the wrong complained of. Under the alter ego theory, it must be shown the parent dominated and controlled the corporation to such an extent that the corporation's independent existence was in an alter ego of the corporation. Under the agency theories, it must be shown the parent exercises control to the extent the subsidiary manifests no separate corporate interests of its own and functions solely to achieve the purposes of the dominant corporation.

[16] As an aside, in Tevas SJ Brief (Doc. No. 2565-1), TPL asserted the Court lacked personal jurisdiction over it because it did not make, sell, or distribute VCDs in the US, that it is not at home in any US jurisdiction, and that TPL's relationship to the TPP Trial Claims is as an indirect (again an undefined term) parent corporation. For several reasons, the Court would have found

3.0 Legal Standard

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Fed. R. Civ. P.* 56(c). An issue is "genuine" "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it can affect the outcome of the suit under governing law. *Ibid. See also Dzielak v. Whirlpool Corp.*, 83 F.4th 244, 250, 259 (3d Cir. 2023) *citing SodexoMAGIC, LLC v. Drexel Univ.*, 24 F.4th 183, 203–04 (3d Cir. 2022) [*quoting Anderson*, 477 U.S. at 248]; *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) and *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n. 3 (3d Cir. 1988) [*quoting* same].

In bearing the initial burden of proof, the movant must present those portions of the record it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-323 (1986). If the movant so demonstrates, the burden shifts to the non-moving party to "set forth specific facts showing that there is a genuine issue for trial" (*Fed. R. Civ. P.* 56(e); *Celotex*, 477 U.S. at 324)) through affidavits or otherwise as provided by *Rule 56* and "identify those facts of record which would contradict the facts identified by the movant." *Port Auth. of N.Y. and N.J. v. Affiliated FM Ins. Co.*, 311 F.3d 226, 233 (3d Cir. 2002). If the non-movant fails to do so, the Court must grant summary judgment. *Big Apple BMW v. BMW of North America,* 974 F.2d 1358, 1363 (3d Cir. 1992). In meeting its burden of persuasion , the non-moving party "may not rest upon the mere allegations or denials of" its pleadings and must present more than just "bare assertions, conclusory allegations or suspicions" to establish the existence of a genuine issue of material of fact. *Fed.R.Civ.P. 56(e).*

The evidence introduced to defeat or support a motion for summary judgment must be capable of being admissible at trial. *Callahan v. AEV, Inc.*, 182 F.3d 237, 252 n. 11 (3d Cir.1999) [*citing Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co.*, 998 F.2d 1224, 1234 n. 9 (3d Cir. 1993)]. Speculation, conclusory allegations, suspicions, or mere denials do not suffice to raise a genuine issue of material fact (*Jutrowski v. Township of Riverdale*, 904 F.3d 280, 288-289 (3d Cir. 2018)) nor does reliance on the pleadings. *Anderson*, 477 U.S. at 256. Rather, the non-

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personal jurisdiction over TPL on a general jurisdiction basis (*see Helicopteros Nacionales de Colombia, S.A. v. Hall,* 466 U.S. 408, 415 (1984) [*citing Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437, 438, 445 (1952)] because of:
-Teva's own documents clearly evidencing that TPL's exerted continuous control over quality compliance and oversight by issuing Corporate Standards for, among other things, auditing API Manufacturer (Ps Exhibit:TEVA-MDL2875-00155644);
-TPL's statements of complete corporate unity regarding compliance and risk assessment on its 2023 annual 10K filing on Edgar (The Court acknowledges that listing on the NYSE secures no personal jurisdiction); and
- this Court's official notice of the near identity of TPLs website with Teva USA's website, especially as regards corporate governance, and compliance and integrity.

moving party "must present affirmative evidence ... from which a jury might return a verdict in his favor." *Ibid*.

In evaluating whether a genuine issue of material fact exists, the court considers all facts and ambiguities in the light most favorable to the non-moving party (*Anderson,* 477 U.S. 242, 255; *Burton v. Teleflex Inc.*, 707 F.3d 417, 425 (3d Cir.2013)) and draws all reasonable inferences in their favor. *Burns v. Pa. Dep't of Corr.*, 642 F.3d 163, 170 (3d Cir.2011). The court decides not "the truth of the matter," but whether a genuine issue of material fact necessitates a trial. *Anderson,* 477 U.S. at 242. Therefore, the court neither weighs evidence nor makes credibility judgments as these tasks are for the fact-finder. *Petruzzi's IGA Supermarkets*, 998 F.2d at 1230.

When contradictory, material facts are presented, a genuine issue is raised, which undercuts a decision for summary judgment. However, even with a presentation of contradictory facts, there may be no genuine fact dispute when one party fails "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322–23. When a movant has completely failed to show an essential element of its case, all other facts are immaterial. *Id.* at 323; *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir.1992).

4.0 Breach of Implied Warranty Claim

Preliminary to the discussion on the breach of express warranty and fraud claims and violation consumer protection laws, the Court notes that Ds have successfully shown (Ds Omni SJ Brf, Doc. No. 2652-1:12-16) and Ps have acknowledged (Ps Opp. to Ds Omni SJ Mot., Doc. No. 2606-1:12) that the claim for Breach of Implied Warranty for TPP subclass d is not actionable. The required element of privity between the parties is lacking. Specifically, the TPPs and the API and FD mfrs were not in privity with each other regarding TPPs reimbursement of their insureds' VCDs, which constitutes TPPs economic loss damages. .

Accordingly, the Court **GRANTS** defendants Omnibus motion for summary judgment (Doc. No 2562) that none of ZHP, Teva, or Torrent is liable for Breach of Implied Warranty Claim in TPP subclass group d.[17] By granting Ds Omni SJ Mot. on this claim, the Court makes

[17]The Court does not reach here the issue of whether the VCDs were merchantable. In their Omni SJ Brf. (Doc. No. 2562-1), Ds sought summary judgment on the merchantability of the VCDs under two separate arguments: first, under the breach of implied warranty claim. While granting Ds summary judgment on the breach of implied warranty claim, the Court has made no express finding on the merchantability of the VCDs. Second, Ds raised similar arguments in Section 9.1 *infra* stating Ps had No Cognizable Injury. There the Court has expressly stated Ps worthlessness theory raises a genuine issue of material fact and leaves that for the fact-finder.

no express or implied finding on the merchantability, worthlessness, or value of the VCDs at issue, and further states that no finding, decision, or resolution on the worthlessness or merchantability of the VCDs shall be construed by the Court's grant. Rather, the Court grants Ds Omni SJ Mot. because Ps appear to have expressly withdrawn the breach of implied merchantability claim from the TPP trial. Ps Opp. to Ds Omni SJ Mot.:23.

5.0 Parties Summary Judgment Motions on the Claims

This section summarizes the parties' summary judgment filings. *See also* Tables 1 and 2 *supra.*

Ps Summary Judgment Filings

Plaintiffs filed 2 summary judgment motions. Ps SJ Mot., Doc. No. 2569 seeks summary judgment against all 3 Ds for the claims of breach of express warranty and violation of consumer protection laws ["CPL"s], with accompanying brief Doc. No. 2569-1. The same motion (Doc. No. 2569) also seeks summary judgment against ZHP for the claim of common law fraud, accompanied by brief Doc. No. 2569-2. Ps also filed a summary judgment motion against Torrent (Doc. No. 2559-1) for the claim of common law fraud, with accompanying brief Doc. No. 2559-1.

While not filing an individual summary judgment motion against Teva for the claim of common law fraud, Ps are still asserting it against Teva in the TPP Trial from the Third Amended Consolidated Economic Loss Class Action Complaint (Doc. No. 1708).

Ds Summary Judgment Filings

Defendants have filed one Omnibus summary judgment motion (Doc. No. 2562), with accompanying brief Doc. 2562-1, against Ps seeking all three claims: breach of express warranty, violation of CPLs, and common law fraud be adjudicated as not actionable. Ds Omni SJ Brf. also seeks summary judgment on the following issues relating to plaintiffs' eligibility for damages:

That Ps have no cognizable injury;

That Ps damages model cannot establish class-wide damages;

That Ps cannot prove Ds alleged misrepresentations proximately caused TPPs economic loss;

That Ps cannot prove fraud or warranty based damages; and

That Ps cannot prove punitive damages.

In addition to Ds Omnibus motion, certain defendants have filed individual SJ motions

against plaintiffs. These include:

ZHP SJ motion, Doc. No. 2564 with accompanying brief, Doc. No. 2564-1, on issues relating to the fraud claim and particularly that:

ZHP VCDs were not adulterated;

Ps cannot prove fraud;

Ps cannot show scienter, therefore cannot be awarded punitive damages.

ZHP also seeks summary judgment that ZHP China and Huahai U.S. bear no liability for any of the three claims. For discussion of this argument, *see* section 2.1 *supra*.

Teva SJ motion, Doc. No. 2565 with accompanying brief, Doc No 2565-1, on very similar fraud claim issues as ZHP's motion, particularly that:

Teva VCDs were not adulterated; and

Ps cannot show scienter, therefore Ps cannot be awarded punitive damages; and

Torrent SJ motion (Doc. No. 2570) with accompanying brief, Doc. No. 2570-1, on very similar fraud arguments as ZHPs and Tevas, particularly that:

Torrent VCDs were not adulterated; and

Ps cannot show scienter, therefore Ps cannot be awarded punitive damages.

6.0 Breach of Express Warranty

6.1 Background to Ps Breach of Express Warranty Claim

For the TPP Trial, the only mfr of generic valsartan API is ZHP, which produced the API in China. The U.S. subsidiary of ZHP, Prinston, holds one or more Abbreviated New Drug Applications ["ANDA"][18] for generic valsartan API and FDs, which are listed in the FDA's Orange Book.[19]

ZHP API became contaminated with genotoxic carcinogens, NDMA and NDEA, when ZHP changed its manufacturing process twice after about 2011. ZHP sold its API to Teva and Torrent and these FD mfrs put the ZHP API into pills. Contaminated VCDs were marketed and sold by ZHP and its subsidiaries as well as Teva and Torrent in the U.S. market since at least 2015. Generic valsartan is a prescription drug only and a drug of choice for treating high blood

[18] The FDA approves a generic drug product for inclusion in the Orange Book when it has been the subject of an ANDA, which is a request to the FDA to make and market a generic drug in the U.S. The ANDA does not require the applicant to conduct clinical trials. A fundamental criterion of Orange Book inclusion is that the ANDA-approved drug must be bioequivalent to the brand-name drug or Reference Listed Drug ["RLD"], which the applicant shows by testing its drug against the brand-name version on a small group of test subjects.

[19] The publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the List, commonly known as the **Orange Book**), identifies drug products that the FDA under the Federal Food, Drug, and Cosmetic Act ["FD&C Act"] has approved on the basis of their safety and effectiveness.

pressure. Before the FDA became aware in July 2018 of the nitrosamine contamination in VCDs made with ZHP API and the voluntary recalls began removing VCDs from the U.S. market, most valsartan pills sold in the U.S. contained ZHP API. Thus, many U.S. consumers with high blood pressure were taking contaminated VCDs. When the nitrosamine-contamination became known, physicians, and indeed the FDA, scrambled to give reliable advice to consumers about continuing to take the contaminated VCDs. The "scrambling" was because the FDA had calculated that taking the highest dose of contaminated VCD for about 4 years increased a consumer's risk of cancer to 1 in 8000. The implicated cancers were more likely to be liver, lung, and stomach. The VCD contamination in the U.S. market was considered frightening, dangerous, and anxiety-provoking[20] as physicians and consumers weighed the health benefit of keeping their blood pressure lowered to avoid stroke and heart failure against the increased risk of developing cancers with high morbidity and mortality rates.

Not only validating ANDA generic drug applications and approving sale of the generics, the FDA continues its efforts through the life cycle of drug manufacturing and marketing to ensure the quality of generic drugs. In fact, the ANDA approval process includes not only the FDA's testing that the drug composition itself is safe and equivalent to the RLD, but also FDA oversight that the generic mfr complies with Current Good Manufacturing Practices ["cGMPs"]. cGMPs come from several sources, the most important of which is the Code of Federal Regulations specific to the Food Drug and Cosmetic Act ["FD&C Act"] and which detail how to comply with the FD&C Act.[21] FDA assessors and investigators rely on federal cGMP regulations to determine whether the generic mfr has the necessary facilities, equipment, and capability to manufacture the drug it intends to market.

The federal cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a generic drug product. Importantly, an ANDA is often accompanied by a Drug Master File ["DMF"], which a generic manufacturer submits to the FDA to give confidential, detailed information about facilities, processes, or materials used in the manufacturing, processing, packaging, and

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[20] Patrice Wendling, *Generic Valsartan Abandoned After Recalls, ED Visits Rise*, MEDSCAPE, November 13, 2019.

[21] The relevant portion of the U.S. Code of Federal Regulations ["CFR"] is in Title 21, which interprets the FD&C Act and related statutes. The pharmaceutical or drug quality-related regulations appear in several parts of Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299.These regulations describe the regulatory requirements that ANDA applicants and drug manufacturers must follow. In particular, the relevant regulations for the TPP Trial can found here:
21 CFR Part 314 For FDA approval to market a new drug.
21 CFR Part 210. Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs.
21 CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals.

storing of their generics. For ANDAs from a foreign manufacturer, DMFs are required. Although not formally approving DMFs, the FDA does review them as a source of reinforcing information in its approval of an ANDA.

Throughout the period when the mfr makes the ANDA-approved generic, FDA investigators are expected to regularly monitor the compliance of drug manufacturers with cGMPs. For generic mfrs outside the U.S., such monitoring includes site visits by FDA investigators who review the entire manufacturing process, including the manufacturing facilities and the administrative / corporate / quality assessment / risk prevention procedures for ensuring fail-safe quality and purity in their generic drugs. As federal regulations, these cGMPs aim to ensure a generic drug is safe by requiring the drug to actually contain ingredients and exhibit the strength and efficacy the manufacturer tells consumers and insurers that it has.

Federal cGMP regulations are such important regulatory requirements for generic drug mfrs, whether foreign or domestic, that when a drug mfr fails to comply with these, their API and FD pills become unsafe. The Orange Book lists the chemical composition of the RLD to which the composition of the accompanying generic must match in terms of chemical formula and amounts of each element. Generally, inclusions of chemical ingredients other than those listed in the Orange Book does not mean the generic is removed from the Orange Book or recalled from the market so long as these ingredients, also called impurities, do not affect the relative equivalence of the generic to the RLD. Almost all generics contain "impurities", ingredients that differ from the RLD. However, when the generic drug contains a harmful impurity not listed in the RLD, the generic is said to be "contaminated", which is not necessarily a term of art but useful to distinguish that a generic drug that will be recalled from one containing mere impurities.[22]

Besides the cGMPs found in the federal regulations of the FD&C Act that generic mfrs must comply with, cGMP requirements are found in other statutes and accompanying regulations. By no means does the FDA exclude these in its regulatory regime but actually explains these in special documents called FDA guidances,[23] which can also become requirements for drug mfrs. In addition, the U.S. Pharmacopeial Convention is a private, non-governmental organization that publishes the United States Pharmacopeia ["USP"] and the National Formulary ["NF"] as official compendia of the United States. Much of the USP and NF

[22] These paragraphs on FDA background, etc. come directly from information provided on the FDA's own website, last accessed 13 March 2024.

[23] *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. (Last accessed 13 March 2024).

is legally enforceable,[24] meaning generic drug mfrs have to comply with the compendia of these organizations. Under Federal law, a drug with a name recognized in USP–NF must comply with the current version of compendial standards deemed official by USP, or risk being deemed adulterated, misbranded, or both. *See FD&C Act §§501(b)* and 502(e)(3)(b) and the corresponding FDA regulations at *21 CFR 299.5(a & b)*. Drugs recognized in the USP must comply with identity standards as well as with standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs. *See FDCA 501(b)* and the corresponding Federal regulations at *21 CFR 299.5(c)*.

When the FDA finds that a drug mfr has not complied with required cGMP regulations or USP compendial standards, it has the authority to issue various regulatory actions, including an FDA Form 483 observation ("inspectional observation") or a Warning Letter. After conducting a routine inspection of a mfr's plant, the FDA inspector may issue a 483 observation to describe any one or more of a wide array of potential regulatory violations relating to the overall facility, equipment, processes, controls, products, employee practices, and/or records. Most common reasons for a 483 observation include safety, quality, testing procedures not fully followed and poor or inadequate investigations of discrepancies or failure found in the drug product or the manufacturing process.[25]

If the mfr does not demonstrate complete resolution of the problems raised in the 483 observation, the FDA escalates its engagement by issuing a Warning Letter, which is a regulatory action limited only to violations / deviations from the *FD&C Act §501* (*21 U.S.C. 351*) related to human drug manufacturing. The generic mfr is obligated by law to rectify the violations described in a Warning Letter.

Besides dealing with the FDA for violations of cGMPs, if a generic drug manufacturer fails to comply with federal cGMP regulations and guidances and USP compendial standards in their manufacturing practices, they can be sued for various legal claims. Such legal claims arise from the manufacturer's mislabeling, also known as misbranding, either the ingredients, or ingredient quantity, or the generic pill's purity, safety, equivalence to the RLD to which it must closely conform. Plus, legal claims can arise from the manufacturer's non-compliance with cGMP guidelines. For clarity, it is compliance with cGMPs that ensure drugs are safe to market.

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[24] Except that USP general chapters numbered above 999 provide only general information and do not contain any mandatory requirements. General information chapters might include some recommendations that may help a firm meet cGMP requirements.

[25] The generic mfr must respond to a FDA 483 observation in writing within 15 days. The FDA inspector often provides on the spot a draft inspection report, known as an Establishment Inspection Report, or EIR.

Grounded in the failure to comply with cGMPs or compendial standards, legal claims against generic drug mfrs can include breach of express warranty, violation of consumer protection laws, and fraud. And, these claims are precisely what Ps have asserted against ZHP as the API mfr and Teva and Torrent as the FD mfrs.

Importantly to Ps claims, when the evidence shows a generic drug manufacturer has failed to meet cGMP regulations and USP compendial standards in the manufacturing or marketing of its drugs, the drugs are deemed **adulterated** under federal law, *21 U.S.C. ¶¶351*, which states in relevant part:

> "*21 U.S. Code § 351 - Adulterated drugs and devices*
>
> A **drug or device shall be deemed to be adulterated**—
>
> (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture
>
> ....
>
> (2) ...(B) i**f it is a drug** and the methods used in, or the facilities or controls used for, its **manufacture, processing, packing, or holding do not conform to** or are not operated or administered in conformity with **current good manufacturing practice** to assure that such drug meets the requirements of this chapter **as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess** ...
>
> (b) Strength, quality, or purity differing from official compendium
>
> If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or **its quality or purity falls below, the standard set forth in such compendium**." [emphasis added]

21 U.S.C.§351(a)(2)(B) and (b).

6.2 Whether Defendants Expressed Warranties to TPPs

The above discussion contextualizes the bases for Ps claims of breach of express warranty, violation of consumer protection statutes, and fraud. These claims arise from Ps assertions that all 3 defendant manufacturers failed to comply with cGMPs in making the VCDs and in testing their safety and purity equivalence to the RLD. Ps further assert that Ds knew their VCDs did not so comply, which, Ps aver, grounds their fraud claim.

Moreover, because of their individual cGMP failures, the VCDs should be deemed adulterated under federal law. Because of that adulteration, everything Ds expressed about the VCDs equivalence to the RLD in terms of safety, quality, even identity constituted

warranties about those qualities, which were breached because Ds statements were false, deceptive, and fraudulent.

As for the breach of warranty claim, Ps Omni SJ Brf., Doc. No. 2569-1:2 seeks summary judgment on the following issues:

-that Ds failed to meet cGMPs and compendial requirements in making and testing the VCDs for quality and safety;

-that such failure rendered the VCDs adulterated;

-that Ds branding their VCDs as generic valsartan expressed a warranty that the VCDs were equivalent to the RLD in terms of quality and safety, which Ds breached because their VCDs were adulterated;

-that, since the VCDs were adulterated but not revealed to contain nitrosamines until July 2018, had the FDA known of the adulteration, the VCDs would not have been sold from the time of contamination and were unmerchantable;

-that TPPs reimbursed for unmerchantable VCDs from 2015 to the time of VCD recall, they are owed damages in the amount of what they paid for their insureds VCDs.

Ps cite this Court's Motion to Dismiss Opinion ["MTD"] 3 as support that Ds very naming of their VCDs and marketing them in the marketplace as valsartan rose to a warranty of the VCDs purity, safety, and equivalence to the RLD. Ps aver, as in their Motion to Dismiss arguments, that each D affirmed and described their FD VCDs as FDA approved "valsartan", which, because of how the Orange Book identifies generic drugs, expressed "valsartan" as the generic or therapeutic equivalent of the RLD, Diovan®.[26] Ps Omni SJ Brf:6-8. Ps also aver Ds

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[26] In its Preface to the Orange Book (Current Edition), the FDA explains what the Orange Book is and how it's intended to be used.

> "…The FDA Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product. In addition, the Orange Book contains **therapeutic equivalence evaluations** for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and **advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection** and to foster containment of health care costs. "

See https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface#tecode. (last accessed 4 Mar 2024).

Moreover, a search for "valsartan" in the Current Orange Book listings shows that Discontinued VCD products no longer have AB status, which is that status the FDA applies to generics it considers to be therapeutically equivalent to another product. (https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm) (last accessed 4 Mar 2024).

> Interestingly, also in its Preface to the Orange Book (Current Edition), the FDA states:
> **"Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act. "** [emphasis added].

Thus, the FDA's own statements create a once and future confusion about the legal meaning of its therapeutic equivalence ["TE"] evaluations. On the one hand, TEs are meant to promote guidance on drug selection—which could be argued sets forth a warranty about the generics pharmaceutical equivalence to the RLD. On the other hand, TEs are apparently not intended as

use of Orange Book descriptions of their product as valsartan warranted that their VCDs were therapeutic equivalents ["TEs"] of the RLD. *Id.*:7-8.

At the motion to dismiss stage, the Court found it important not to dismiss Ps claim of express warranty breach. There Ps had successfully argued the drug mfrs' labelling of its drug with the same name as the RLD could stand as a warranty because of TPPs, unable to independently confirm they paid for uncontaminated valsartan, relied on Ds statements.

Ds assert Ps cannot prove Ds made an express warranty on which TPPs relied (Ds Omni SJ Brf.: 16-18) and further argues Ps cannot even prove each D made express warranties (Ds Opp. Brf: 7-12). Ds aver that this Court's MTD 3 opinion cannot support that Ds made such warranties. *Ibid.* In the alternative, Ds assert, even if the Orange Book label does express a warranty, since their VCDs contained only trace levels of NDMA or NDEA, Ds cannot have not violated any such purported warranty. The VCDs remained pharmaceutically equivalent and bioequivalent to the RLD. Ds Opp. Brf. Ps SJ Brf.:17, *citing* the Class Cert. Op. The Court points out that Ds citation to its Court's Class Cert. Op. does not support their "bioequivalent" assertion. In its Class Cert. Op., the Court expressly refused to wade into the meaning of bioequivalence or therapeutic equivalence, leaving those terms for the fact-finder to define. Ds assertion is just that, nothing more.

The Court finds a genuinely disputed, material fact is whether Ds labelling of the VCDs by the Orange Book designation "valsartan" signifies Ds warranty as to the purity, identity, or any other quality of the VCDs. Other genuinely disputed, material facts relate to Ps assertions that other of Ds statements were also warranties: in particular, that VCD package inserts, product labels, medical and clinical literature, websites, etc., affirmed that VCDs were FDA approved and/or USP compliant, and/or had an AB therapeutical equivalent rating in the Orange Book.

Ps SJ Brf.:6-11 asserts that each D independently described its VCDs as their finished dose VCDs as FDA approved "valsartan" that was the generic or therapeutic equivalent of DIOVAN® or EXFORGE®, and that their product met all compendial requirements. ZHP Opp. SOMF:¶¶26-34, 145-54, 146.5, 154.5; Torrent Opp. SOMF:¶¶ 32, 36-38, 57; Teva SOMF:¶¶ 37-40; *see* Teva Opp. SOMF:¶34 on ZHPs agreement with Teva to provide non-adulterated, non-misbranded API. Ps SJ Brf.:7-8 also asserts that statements by other means were also warranties. Ps aver that Ds also breached these other warranties because of their non-compliance with FDA cGMPs (Ps SJ Brf:8-18) and USP compendial standards (*Id.*:18-22). The legal result of Ds non-compliance, Ps argue, is that their VCDs were adulterated by law

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"official evaluations" (whatever that means), which clearly gets the FDA off the hook of legal liability for any inaccurate TEs, such as those for the contaminated VCDs before the contamination was discovered.

because every sold VCD was contaminated with nitrosamines. *Id*.at 22-26.

Ds dispute whether their identifying VCDs or labelling / packaging them as valsartan rose to the level of a warranty, relying on the deposition testimony of Summacare's and Emblem Health's *Rule 30(b)(6)* corporate representatives who testified that they personally did not receive any of Ds statements about VCDs nor did they believe the TPPs received warranties about the VCDs directly from Ds. *See* Ds SOMF:¶¶84-85. However, Ds argument goes to the element of reliance on the warranties, which is discussed *infra*, and actually sidesteps whether Ds statements in labels, websites, literature, etc. expressed warranties of the safety and purity equivalence of the VCDs to the RLD.

In disputing that their contaminated VCDs were adulterated, Ds imply that naming the VCDs "valsartan" could not have been a breach of warranty. *See* Ds SOMF:¶¶70, 89, which states without more that the VCDs were pharmaceutically equivalent to the RLDs and thus the impurities were *ipso facto* within acceptable limits, which is an argument advanced by one of Ds experts.[27] Additionally, Ds dispute whether the nitrosamine contamination was even sufficiently high to be deemed anything other than an impurity and thereby acceptable by FDA and USP compendial standards. Torrent Opp. SOMF:16; Teva Opp. SOMF:¶8.[28] In not directly addressing whether their statements were warranties, Ds skip to the issue whether Ds breached such warranties. The Court finds that the issue of whether Ds statements, wherever expressed, were warranties is not genuinely disputed and is a material fact. The Court agrees with its MTD 3 Opinion and with Ps declarations (SJ Omni Brf.:7) that Ds labelling of the VCDs as valsartan constituted an express warranty.

Accordingly, the Court **GRANTS** plaintiffs' Omnibus motion for summary judgment (Doc. 2569) on the issue that defendants' affirmations, statements, labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the RLD.

6.3 Whether Ds Breached their Express Warranties to TPPs- Substantive Issues: Whether VCDs Were Adulterated

The discussion moves to whether a genuine dispute of material facts exists as to Ds

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[27] Whether the VCDs were adulterated is discussed in the next section *infra* on whether warranties were breached.

[28] *See* Ds SOMF:¶70,stating that, when first discovered in the VCDs, the amounts of NDMA and NDEA were within the limits of the FDA-approved specifications for unknown impurities during the entire period before recalls. *See also* Ds SOMF:¶¶75-76, stating interim limits for NDMA and NDEA contamination were published by the FDA until December 2019 and by the USP until September2020; *but see* ZHP Opp. SOMF:¶30, stating that all valsartan batches ZHP tested exceeded the FDA limit for NDMA. The Court recognizes a genuine dispute exists over material facts of the extent of NDMA/ NDEA contamination of the VCDs before recall, which may implicate the amount of damages. But again these arguments do NOT go to the issue of whether Ds statements WERE warranties, but to whether the warranties were breached, discussed in the next section *infra*.

breach of their express warranties. The parties' arguments showcase a vigorous back and forth of disputed facts regarding whether there was a breach of warranty, whether Ds complied with cGMPs and required standards, and whether VCDs were adulterated,.

In arguing for Ds breach of express warranties, Ps SJ Omni Brf. puts forward this syllogism:

- All Ds marketed their VCDs as valsartan,

  which made an express warranty that the VCDs sufficiently complied with the safety and purity profile of the RLD;

- Since ZHP did not comply with cGMPs / compendial standards in making and testing its API,

- its API was ADULTERATED by law;

- Also, since none of ZHP, ZHPs U.S. subsidiaries, Teva or Torrent complied with cGMPs for testing the contaminated API before making contaminated pills and marketing/selling them in the U.S.;

-the finished dose VCDs sold before recalls in July 2018 were **adulterated as a matter of law under the FD&C Act**; [29]

-Therefore, marketing and selling **adulterated** VCDs breached Ds expressed warranties that their sold drugs were the equivalent in safety and purity to the RLD.

To keep this opinion streamlined, the Court provides only an overview of the parties' arguments whether Ds breached their express warranties. Ps assert ZHPs valsartan API became adulterated by law because ZHP created two new processes for making the API and in each changed the solvent (i.e., a starting point) as well as the chemical reagent for extracting that solvent at the end of the process. The changed manufacturing processes differed from those ZHP had originally described in its DMF that accompanied Prinston's ANDAs. The new solvents reacted with the solvent extractors in ways that ZHP did not adequately test for or

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[29] Drug adulteration is statutorily defined:

> (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture…
> … (2)…(B) **if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to** or are not operated or administered in conformity with **current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess**; ….
>
> (b) Strength, quality, or purity differing from official compendium
> If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, **or its quality or purity falls below, the standard set forth in such compendium.** ….

21 U.S.C. §. 351(a)(2)(B), (b). [emphasis added].

consider; these processes ended up creating degradation products of NDMA and NDEA in the API. ZHP has admitted that the solvent change and addition of a chemical to extract that solvent are the root causes of the NDMA / NDEA contamination in its API.

Ps aver ZHP did not follow the cGMPs required to discover that its changed manufacturing processes would cause nitrosamine formation in the API. In 2015, ZHP began selling the nitrosamine-contaminated API to Teva and Torrent who made finished dose products from it and started selling them. Ps also aver that no FD mfr complied with required cGMPs to test that the API had the safety and purity ZHP claimed it had.

ZHP and the FD mfrs aver they complied with cGMPs for testing and quality assurance because, before the VCD recalls in 2018, it was unknown and/or very difficult to find evidence from reputable chemistry sources that disclosed the likelihood of nitrosamine formation in ZHPs changed manufacturing processes. It was only after the FDA discovered the nitrosamine contamination in Jun 2018 that the FDA itself began to develop a testing regime for nitrosamines in the valsartan API. Each D presents evidence of its compliance with known "industry standards" of testing for nitrosamines during the period of VCDs sales from 2015 to 2018. Ds aver the evidence shows they complied with all cGMPs in the manner that was recognized as sufficient before the recalls in July 2018. Therefore the API and finished dose pills they sold could not have been and were not adulterated by law. Ps aver Ds compliance conduct was not only ineffectual but actually failed known standards before the recalls.

Ds generally, and Torrent and Teva individually, attest that each complied with all cGMPs and USP compendial standards for testing, quality assessment, risk assessment, and manufacturing of the APIs or Finished Doses. Ds SOMF:¶¶15-33; Teva Opp. SOMF ¶26.

But see ZHP Opp. SOMF ¶¶43-51, describing:

FDA's letter dated 21 Sept 2018 to ZHP listing cGMP violations and including a Form 483 letter relating cGMP violations revealed upon the FDA's site visit on 3 Aug 2018 to ZHP's API manufacturing facility;

FDA's letter to ZHP dated 28 Sep 2018 advising of an import ban on ZHPs products until the cGMP violations were righted;

the FDA Warning Letter dated 29 Nov 2018 notifying ZHP of significant cGMP deviations for their API manufacturing operations and that their API was adulterated.

Whether Ds complied with cGMPs is a central issue to the breach of express warranty. If their non-compliance can be shown, then, as Ps aver, Ds API and Finished Doses could be deemed adulterated by law. If undisputed facts show VCD adulteration, then Ds representations that their VCDs were equivalent to the RLD were false, which demonstrates a

breach of express warranty.

Ultimately, then, whether ZHPs API was adulterated is the central fact in dispute in this matter, not only for the breach of warranty claim but for violation of state consumer protection laws and fraud. If the API is found to be statutorily adulterated, then the finished dose products were necessarily adulterated. ZHP Opp. SOMF:¶¶23, 47-51, 164-167; Teva Opp. SOMF¶¶1-25; Torrent Opp. SOMF¶¶ 6-7, 14-15, 23, 25). And that the FD mfrs sold statutorily adulterated VCDS implicates that they did not implement proper quality and risk assessment standards to test ZHP's API.

It is important to note that ZHP and the FD mfrs vigorously argue that, before 28 Nov. 2018, the FDA never declared the API adulterated. Ds argue that, as it is only the FDA that can declare a drug adulterated as a matter of law, the VCDs sold before the recalls in July 2018 cannot be deemed adulterated.

Ps further assert, even without a finding that ZHPs valsartan API was adulterated, the undisputed record establishes that ZHP, Teva, and Torrent each independently violated CGMPs and could not assure the quality of their respective VCDs, and therefore Ds breached their express warranties.

6.3.1 Genuine Disputes of Material Facts: Specific

Regarding whether ZHP complied with cGMPs and USP compendial requirements, the Court finds a genuine dispute of material fact exists and is raised in ZHPs Opp. SOMF¶¶:57-58, 60, 61-62, 65, 76, 80, 85-75, 95.5. These paragraphs relate to, among other things, the specifics of ZHPs inadequate quality testing on the degradation of the solvent Dimethylformamide to NDMA as well as the overall inadequacy of ZHPs risk assessments and quality procedures for its API.

Regarding whether Teva complied with cGMPs and USP compendial requirements, the Court finds that a genuine dispute of material facts exists and is raised in, among other places, Tevas Opp. SOMF ¶¶:26-29, 33-34,42, 44, 48,51-54, 56-57, 60-69, 71-74, 79, 89-90, 92- 103. These paragraphs relate to, among other things, disputes about:

-whether Teva actually tested ZHPs API

-what testing Teva should have applied;

-whether such testing was required because there was no industry-wide knowledge of the degradation of ZHPs new solvent into NDMA at that time;

-the adequacy of Tevas monitoring of ZHP periodic audits; and

-Tevas possible knowledge about the contamination of the API before ZHPs voluntary recall.

Regarding whether Torrent complied with cGMPs and USP compendial requirements, the Court finds that a genuine dispute of material fact exists and is raised in, among other places, Torrent Opp. SOMF ¶¶9-16, 50. These paragraphs relate to Torrent's compliance with cGMPs that required it to test the API independently for contamination, and specifically to:
-whether, before ZHPs first notice in June 2018 to Torrent of the API contamination, Torrent had ever independently tested the API for nitrosamine contamination;
-whether Torrent was required to do so by cGMPs or industry standards; and
-whether, after ZHPs first notice, Teva ever independently tested the AP; and
-whether Torrent should have been independently testing immediately after ZHPs first notice because ZHP gave Torrent a second notice that certain batches of API previously thought uncontaminated turned out to be so.

6.3.2 Genuine Disputes of Material Facts: General

Besides the fact disputes described above, which relating specifically to each defendant, the Court also finds these more generalized disputes of fact: .

-whether warranties were breached because Ds did not conduct sufficient quality control testing for nitrosamines and whether cGMPs, USP compendial standards required such testing;

-whether Ds should have known from chemical standards or literature that more stringent testing methods than their industry standard were required for nitrosamines;

-whether Ds chemists should have known the changes to the API manufacturing solvents and in the solvent extraction process would result in solvent degradation that formed nitrosamines in the API;

-whether, because of Ds lack of testing etc., the APIs were statutorily adulterated from the time the contamination occurred.

6.3.3 Summary of Genuine Disputes of Material Facts

Summarizing the above specific and general genuine disputes of material facts above, the Court finds the following:

there is a genuine dispute of material facts whether Ds breached their express warranties before the recalls of 2018;

there is a genuine dispute of material facts whether Ds complied with all required cGMPs and compendial standards before the recalls of 2018;

there is a genuine dispute of material facts whether the VCDs were adulterated from the sale of contaminated VCDs in 2015.

Accordingly, the Court **DENIES** Ps motion for summary judgment (Doc. No. 2569) and Ds motion for summary judgment on the issues of:
-whether Ds breached their express warranties to Ps;
-whether Ds violated cGMPs and compendial standards in making nitrosamine-contaminated API and FD VCDs and in marketing and selling them before the recalls began in July 2018, and
- whether Ds API and VCDs were adulterated before the recalls began in July 2018.

The Court **DENIES** ZHPs, Tevas, and Torrents individual motions for summary judgment (Docs. No. 2564, 2565, and 2570, respectively) on the issue whether the VCDs sold before the recalls began in July 2018 were adulterated.

6.4 Breach of Express Warranty-Procedural Issue: Lack of Pre-Suit Notice

In addition to their argument that Ps have failed to show a substantive breach of express warranties, Ds assert (Omni SJ Brf., Doc. No. 2562) the express warranty claim fails as a matter of law because of failure to prove required claim elements, including:

-Ps did not give pre-suit notice of the claim to Ds Omni SJ Mot.; and

-In some jurisdictions, Ps breach of warranty claim is time-barred for not being pled within the relevant statute of limitations;

-Lack of evidence that Ds expressed a warranty to Ps. (Section 6.2 *supra* resolves this issue).

-ZHPs SJ Brf. (Doc. No. 2564) also asserts Ps breach of warranty claim fails as to ZHP China and Huahai because neither could have made warranties to the TPPs as neither sold VCDs in the U.S. (Section 2.1 *supra* resolves this issue).

Ps dispute they have not met their burden on this claim, asserting they have put forth material facts that indisputably show compliance with the claim standard. In effect, the Court is asked to decide as a matter of law whether Ps have proved pre-suit notice and timeliness of their warranty claim.

Before a buyer of goods [which include prescription drugs] can bring a breach of warranty claim, *Section 2-607(3) of the Uniform Commercial Code* requires that the buyer "within a reasonable time after [they] discover[] or should have discovered any breach[,] notify the seller of breach or be barred from any remedy." When a party has accepted goods it regards as not complying with a stated warranty and before it can file a legal claim, it must first notify the seller of the alleged breach within a reasonable time of discovering the breach.

Ds argue this Court's finding in its MTD 3 that Ds voluntary recalls functioned as pre-suit notice was incorrect. They assert that *In re Ford Motor Co. Speed Control Deactivation Switch Products Liability Litigation*, MDL 1718, 2007 WL 2421480 (E.D. Mich. 24 Aug 2007) declared recall notices were insufficient as pre-suit notice and demonstrates that the law is well-settled in that respect. However, this Court finds that *In re Ford* and its cited reliance of *Perona v. Volkswagen of Am.*, 684 N.E.2d 859 (Ill.App.Ct.1997) and *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584 (Ill. 1996) do NOT support Ds blanket assertion that recall notices are never sufficient as pre-suit notice.

To be clear, the facts in *In re Ford, Perona,* and *Connick* concerned very generalized recall notices of car manufacturers themselves. Interestingly, these courts found the manufacturers' own recall notices were not specific enough to put even the manufacturers on notice of the specific problems that car owners were experiencing. [30] In *In re Ford,* the subject of the voluntary recall was a faulty, or non-functioning, or dangerous speed control deactivation switch. The car manufacturers' voluntary recall notices spelled out neither the specific mechanical problem nor the specific cause, but issued but a general recall of cars made with a certain period, stating only that the recall related to the speed control deactivation switch. The *Ford* Court followed *Connick* jurisprudence in requiring the car owner to notice the manufacturer with sufficient information to allow it to fix the buyer-complained-of problem, and thereby comply with the warranty on the part and/ or the car.

That is manifestly <u>not</u> the situation here with contaminated drugs, where pre-suit notice does not operate as in a mechanical failure to allow the API or FD mfrs to "fix' the problem. Considering the vast differences in warranty fulfillment between automobile parts and contamination drugs, the Court finds there are quite limited reasons for recalling a drug: it is dangerous, does not work as labelled, or has unknown contraindications that cause unintended health consequences. All of these limited reasons for a drug recall translates into the buyer's needing to give much less information to the seller as adequate pre-suit notice. The Court also finds that a recalled drug for nitrosamine contamination cannot be remedied like a car part so as to fulfill warranty obligations. Accordingly the Court finds pre-suit notice to a pharmaceutical manufacturer need not be as specific as that required to a car manufacturer.

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[30] The *Ford* Court discussed that plaintiffs, while not giving Ford any notice, alleged individual notice was unnecessary, because Defendants had knowledge of the nature of the alleged defect. The Ford court relied on *Perona v. Volkswagen of Am.*, 684 N.E.2d 859, 863 (Ill.App.Ct.1997) to find that recall notices do not satisfy the notice requirement. It quoted that: "Even if a manufacturer is aware of problems with a particular product line, the notice requirement of *§2–607* is satisfied only where the manufacturer is **somehow apprised** of the trouble with the particular product purchased by a particular buyer." *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584 (Ill, 1996).

In addition, unlike with the car manufacturer recalls, the voluntary recalls by the valsartan drug mfrs in July 2018 identified the specific reason for the recall, which was nitrosamine contamination. The follow-on FDA press releases and recalls could not have been more specific about its cause, stating that the FDA's goal was to protect consumers.

The FDA press release dated 13 Jul 2018,[31] describing the voluntary recalls specifically named Solco (a ZHP subsidiary) and Teva, stating:

> "The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan, used to treat high blood pressure and heart failure. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." ...
>
> "We have carefully assessed the valsartan-containing medications sold in the United States, and we've found that the valsartan sold by these specific companies does not meet our safety standards. **This is why we've asked these companies to take immediate action to protect patients,**" said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.
>
> The FDA will continue to investigate this issue and provide additional information when it becomes available. The agency encourages patients and health care professionals to report any adverse reaction to the FDA's MedWatch program." [emphasis added].

Clearly, the FDA's opening notice on 13 Jul 2018 identified with specificity the reason for the recall and the cause. Moreover, the FDA's press release of 30 Aug 2018[32] could not have been clearer or more specific that, already by March 2018, the FDA had issued a guidance[33] about how to conduct risk assessments for identifying genotoxic impurities, including nitrosamines. And if there were any remaining doubt whether Ds were not on notice by this litigation that claimed breach of express warranties, by 11 Dec 2018, the FDA had issued a warning letter to ZHP,[34] which outlined several manufacturing violations at ZHP's Chuannan

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[31] https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (last accessed 2 March 2024).

[32] https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current. (last accessed 3 March 2024)

[33] https://www.fda.gov/media/85885/download (last accessed 3 March 2024)

[34] https://www.fda.gov/news-events/press-announcements/fda-warns-api-manufacturer-involved-valsartan-recall-provides-information-patients-taking-these (last accessed 2 March 2024).

facility [where ZHP made valsartan API] including impurity control, change control and cross contamination from one manufacturing process line to another.

Torrent purchased valsartan API from ZHP. As for Torrent's pre-suit notice, in several communications from 10 Jun 2018 to 17 Aug 2018, ZHP clarified to Torrent that its valsartan API made by both old and new manufacturing processes contained NDMA. Torrent Opp.SOMF:¶¶9-17. By 7 Aug 2018, the European Medical Authority ["EMA"][35] asked Torrent if their FD valsartan product could contain NDEA. *Id*. at 18. By 17 Aug 2018, Torrent initiated a voluntary recall of certain of its VCD finished dose products.[36] *Id*. at ¶ 21. Torrent also initiated a voluntary recall of a related FD product, losartan.[37]

Combining the FDA's 13 Jul 2018 press release, its 30 Aug 2018 press release identifying its March 2018 risk assessment guidance, and its 11 Dec 2018 warning letter to ZHP as a body of specific information provided to ZHP as well as to Teva and Torrent, the Court finds there was sufficiently detailed and full pre-suit notice that not only personal injury law suits were coming but also economic loss ones as well.

Even though the discussion could end here, the Court continues to plumb the *Ford* line of cases to examine how that jurisprudence, cited by Ds, demonstrates the sufficiency of Ps pre-suit notice. In particular, the Illinois Supreme Court in *Connick v. Suzuki Motor Co. Ltd.*, 675 N.E.2d 584 (Sup. Ct. Ill. 1996)[38] held that direct notice to the seller is not required when

(1) the seller has actual knowledge of the defect of the particular product; or

(2) the seller is deemed to have been reasonably notified by the filing of the buyer's complaint.[39] *Connick,* 174 Ill.2d at 589. The *Connick* holding directly relates to the manner of satisfying the pre-suit notice requirement when affirmative pre-suit notice by the buyer has been excepted. *Connick* gives a workable standard for determining when proper pre-suit notice has been given for a breach of express warranty claim but not directly by the buyer to the seller. The Court finds the *Connick* two-prong approach may be satisfied in the alternative and is not only legally adequate but equitably fair to determine when the buyer need not give direct pre-suit notice to the seller. Further, the

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[35] The European Unions' counterpart to the U.S. FDA.

[36] *See* the FDA update of 22 Aug 2018 on Torrent's voluntary VCDs recall at the URL in fn. 34.

[37] Moreover, by 3 Jan 2019 Torrent had voluntarily issued its first recall of losartan pills and stated their recall was due to the detection of contamination with NDEA.

[38] which *Ford* cited for legal support of its holding.

[39] "There are instances, however, when a buyer can fulfill the notice requirement without giving direct notice to the seller. Direct notice is not required when (1) **the seller has actual knowledge of the defect of the particular product** (*Malawy v. Richards Manufacturing Co.,* 150 Ill.App.3d 549, 103 Ill.Dec. 355, 501 N.E.2d 376 (1986)); or (2) the seller is deemed to have been **reasonably notified by the filing of the buyer's complaint alleging breach of UCC warranty.**" … *Connick v. Suzuki Motor Co. Ltd.*, 675 N.E.2d 584, 589 (Sup. Ct. Ill. 1996). [emphasis added].

Court observes that *Connick* combines prong 1 and 2 into a generalized standard for excepting direct notice to the seller:

> "Thus, even if a manufacturer is aware of problems with a particular product line, the notice requirement of [*UCC] section 2–607* is satisfied only where the manufacturer is **somehow apprised** of the trouble with the particular product purchased by a particular buyer.

Id. at 590 [emphasis added].

As for *Connick* prong 1— seller has actual knowledge of the defect—the Court finds that prong satisfied by the FDA press releases and warning letters issued throughout 2018 and beyond. Even though the *Connick* prongs are stated in the alternative, the Court chooses to consider them additively to shape a more stringently considered analysis. As for *Connick* prong 2—filing a complaint in a reasonable period after becoming aware of the problem—on 14 Dec 2018, MSP, Ps class representative here, filed a TPP class action complaint[40] against ZHP and Teva, which included Count 2, Breach of Express Warranty. On 14 Feb 2019, the Judicial Panel on Multi-District Litigation transferred MSPs 18-cv-25260 filing into the MDL. Four months later, on 17 Jun 2019, Ps filed their First Amended Consolidated Complaint (["1st Consol. Compl."], Doc. No. 121:¶¶437-445) against all Ds, which included a breach of express warranty substantially similar to that filed by MSP in December 2018. The Court is not stating the filing of the 1st Consol. Compl. is the reasonable date when Ds had specific pre-suit notice. Rather, it relies on the 1st Consol. Compl. only as a yardstick to show MSPs Dec. 2018 filing pleaded fully an express warranty claim.

In probing the third *Connick* prong that combines prongs 1 and 2—that the manufacturer is **somehow** apprised of the trouble with the particular product purchased by a particular buyer, the Court interprets the "**somehow"** as <u>any means</u> that apprises the seller specifically of the warranty problem. Accordingly, the Court finds that the combination of the FDA recall notices starting from July 2018 through September 2018 coupled with MSPs 14 Dec 2018 complaint satisfies beyond quibbling the pre-suit notice prong of the UCC under *Connick* jurisprudence.

To be clear, in applying *Connick*'s 3-prong standard additively instead of disjunctively, the Court more stringently shows that Ps direct pre-suit notice to Ds is in accord with state laws that require pre-suit notice.

The Court therefore holds, for the avoidance of doubt in cases involving contaminated pharmaceuticals, actual notice to the manufacturer of a breach of express warranty <u>may</u>

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[40] *MSP Recovery Claims, Series LLC v. Huahai US Inc. et al.*, 18-cv-25260, Doc. No. 1: ¶¶122-129 (S.D. Fla. 2018).

include drug mfrs' own recalls coupled with FDA notices that identify the effect of the contamination (in this case, increased risk of carcinogenesis) and the cause / suspected cause of the contamination) and/or contra-indication. This means that Ps pre-suit notice date may be as early as 1 Sep 2018, by which time all 3 Ds had initiated recalls and knew of the cause and the suspected breadth of the contamination. *See especially* the FDA update of 30 Aug 2018 and the FDA press release of 13 Sep 2018 containing links to the European Medical Authority and Canadian Medical Authority's discussions on the recalls.

However, the Court applies *Connick*'s third prong to hold that recalls by the drug API or FD mfrs themselves in the fall of 2018 combined with the lawsuit by MSP on 14 December 2018 serve as more than sufficient, detailed evidence that Ds were apprised that the recalled VCDs presented a possibly dangerous situation to consumers and would herald lawsuits for personal injury and economic loss.[41] Since the facts here meet all three of *Connick* prongs alternatively and additively for the buyer's excepted notice, the Court finds that Ps breach of express warranty claim does not fail for lack of notice.

Accordingly, on the issue of pre-suit notice, the Court **DENIES** Ds Omni motion for summary judgment (Doc. No. 2562), finding the evidence shows as a matter of law that Ps breach of express warranty claim does not fail for lack of pre-suit notice.[42]

6.5 Breach of Warranty-Procedural Issue: Statute of Limitations

Ds argue Ps express warranty claims are time-barred because a significant percentage of them between 2012 and 2019 lie outside relevant statute of limitations. The parties dispute various statute of limitations periods and trigger dates for the remaining states in the relevant subclass, listed in Table 3.

[41] Especially after the FDA issued a press release in the Fall of 2018 stating acceptable levels of NDMA and NDEA, the API and FD mfrs would have been put on particular notice that lawsuits would follow for personal injury and economic loss because the FDA had stated the nitrosamine contamination in ZHPs API and sold VCDs exceeded those levels.

[42] Ps Opp.to Ds Omni SJ Mot. (Doc. No. 2606-1:3-4) raised a procedural argument that the Federal Rules of Civil Procedure overpower state laws requiring pre-suit notice. In finding such state law pre-suit notices may be satisfied by the *Connick* exception standard, the Court does not reach this procedural argument.

Table 3: Express Warranty: State Statute of Limitations for TPP Subclass b

No Discovery Rule[43]		Discovery Rule		
4-yr Statute of Limitations ["SOL"]	6-yr SOL	4-yr SOL	5-yr SOL	6-yr SOL
Arkansas, Georgia, Montana, New York, North Carolina, Ohio, Oregon, Rhode Island, Texas, Utah, Vermont, and Wyoming	Mississippi Wisconsin	Nevada	Florida	South Carolina

Ps state:

-Alabama, Arkansas, Georgia, Montana, Nevada, New York, North Carolina, Ohio, Oregon, Rhode Island, Texas, Utah, Vermont, Wisconsin, and Wyoming have codified *UCC § 2-725* (for sales of goods) with a 4-year statute of limitations, starting when delivery is tendered;
-Mississippi and South Carolina have codified *UCC § 2-725* with a 6-year statute of limitations and same delivery date;
- while Florida has not so codified the UCC but adopted a 5-year statute of limitations. Ps Opp.2 Ds Omni SJ, Doc. No. 2606-1:11. Moreover, Ds state that Wisconsin also codified a 6-year statute of limitations and that only Florida applies a discovery rule for an express warranty breach. Ds Omni SJ Brf:11. However, Ps cite to case law that demonstrates, besides Florida, Nevada and South Carolina also have a discovery rule. Table 3 captures all these variations.

For TPPs economic loss claims for breach of express warranty, tender of delivery occurs when the TPP paid for or reimbursed their consumers' VCDs. This date occurs when the consumer paid the pharmacy or dispensary for the VCD script because at that time the dispenser will also charge the TPP for its portion of the reimbursement. Thus, the date of VCD script purchase serves as the trigger date for express warranty statute of limitations.

As stated above, on 14 Feb 2019, the Judicial Panel on Multi-District Litigation

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[43] Uniform Commercial Code § 2-725 Statute of Limitations in Contracts for Sale.

(1) An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued. By the original agreement the parties may reduce the period of limitation to not less than one year but may not extend it.

(2) A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

transferred into this MDL the MSPs class action complaint of 14 Dec 2018,[44] which included Count 2 for breach of express warranty. Under a *Connick* analysis as discussed *supra*, the date of the MSPs complaint serves as the start of the proper and formal pre-suit notice of specific economic loss claims. For absolute clarity, the Court agrees with Ps Opp. Brf. that the pre-suit notice to Ds of the express warranty claim for the TPP Express Warranty subclass b indisputably stands as 14 Dec 2018.

Ps assert also that, if 14 Dec 2018 is deemed the date of pre-suit notice, the statute of limitations for breach of express warranty claims would work backwards from then. Ps rely on ZHPs SOMF:¶24 that the date of the first U.S. sale of VCDs via their US subsidiaries was 2 Oct 2015 and continued through ZHPs recall in July 2018. Torrents SOMF:¶5 states the first U.S. sale of their VCDs was from January 2015 through recall in July 2018. Tevas SOMF:¶1 states the first U.S. sale of their VCDs was from about 21 Mar 2013 through recall in July 2018. In those jurisdictions having the most restrictive statute of limitations—4 years—the breach of express warranty claims would go back to 14 Dec 2014. In those jurisdictions with the least restrictive—6 years—the start date of these claims would be 14 Dec 2012.

Accordingly, on the issue that the statute of limitations limits the breach of express warranty claims in some jurisdictions, the Court **DENIES** Ds Omnibus motion for summary judgment (Doc. No. 2562) and **GRANTS** Ps motion for summary judgment (Doc. 2569). The Court finds that the statute of limitations for express warranty claims in any jurisdiction in TPP Express Warranty subclass b works backwards from the pre-suit notice date of 14 Dec 2018.

Ps Opp. Brf to Ds Omni SJ Mot.:14-17 assertks two arguments for tolling the statute of limitations: 1) fraudulent concealment or equitable estoppel and 2) continuous violation doctrine. Specifically, Ps assert the TPP Express Warranty subclass b states of Alabama, Arkansas, Florida, Georgia, Mississippi, Montana, New York, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin, and Wyoming toll the running of the statute of limitations under a fraudulent concealment or equitable estoppel theory.

Ps fraudulent concealment argument against ZHP is that, when alerted to the nitrosamine contamination at least by 27 Jul 2017, ZHP fraudulently concealed it. It was at least by that date that a ZHP PhD organic chemist had discovered it and notified ZHP management.[45] ZHP Opp. SOMF:¶¶40-42.5. ZHP did not disclose the nitrosamine contamination to the FDA from 27 Jul 2017 until the FDA noticed ZHP in July 2018.

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[44] *See* Doc. No. 1 in this MDL and *MSP Recovery Claims, Series LLC v. Huahai US Inc. et al.*, 18-cv-25260, ¶¶122-129.

[45] This chemist is Li, Jinsheng . Dr. Li was employed at a ZHP wholly-owned subsidiary where he worked in a department tasked with reviewing degradation products in ZHPs manufacturing processes. On 27 July 2017, Dr. Li sent an email to several ZHP management officers and personnel, informing them of the nitrosamine contamination in a precursor of the irbesartan API, a related sartan. The email also states such contamination had already been known for valsartan API. Ps SOMF:40-42.5.

Ps also assert a fraudulent concealment argument against Torrent. On 3 Aug 2018, ZHP revealed to Torrent that its valsartan API was contaminated. Torrent, however, did not immediately disclose to its consumers and customers that its FD products were contaminated but continued to sell them until 17 Aug 2018. Torrent Opp. SOMF ¶15, 21, 53.

All 3 Ds assert they did not know about the nitrosamine contamination before the FDAs notice to them in June 2018. They state they could not have known about it because there was an industry-wide lack of understanding and lack of specific guidance in FDA cGMPs or USP compendial monographs for testing for nitrosamines. Ds also state not until November 2018 could they have independently tested for such contamination. That's when the FDA began coming up with answers for what specific testing methods would disclose nitrosamine contamination in ZHPs manufacturing processes. Ds SOMF:¶¶71-74. ZHP also avers it was unknown to even expect to do such testing as the formation of nitrosamines in ZHPs changed manufacturing processes was completely unexpected. ZHP Opp. SOMF:¶¶41.5-51.

As for the continuous tolling argument, Ps assert that Ds engaged in continuing wrongful conduct by not complying with cGMPs from the time the API manufacturing changes occurred, which gave Ds the opportunity "not to know" their VCDs were contaminated for at least 3 years. Ps Opp. Brf.:17. Although not directly addressing these tolling arguments, Ds assert that whether they complied or not with cGMPs at all or continuously is a genuine dispute of material facts. Ds Opp. Brf:19-24.

Accordingly, as tolling of the statute of limitations for the express warranty claim depends on the genuinely disputed, material fact of whether Defendants did or not comply with cGMPs, the Court **DENIES** both defendants Omnibus motion for summary judgment (Doc. No. 2562) and plaintiffs (Doc. No. 2569) motion for summary judgment. Ps requests to toll the statute of limitations for the express warranty claim will attend the fact-finder's resolution on whether Ds knew of the nitrosamine contamination before the FDAs notice to them and if they concealed it.

6.6 Whether Plaintiffs Relied on Defendants' Express Warranty

Ds also dispute that Ps have not met the required element of reliance for the express warranty claim. Ds primary argument is that no TPP corporate representative testified in their respective deposition that they were even aware of the purported warranties. The TPPs therefore cannot have relied on Ds warranties about the safety and purity of the VCDs. Ds Omni SOMF:¶¶84-85. Ps argue the deposed corporate representatives are not the ones who create TPP formularies and consequently would be unaware of whether Ds expressed warranties or

not about the VCDs.

Even so, Ds counter, in making their formulary decisions, such TPP agents do not consider statements by the drug mfrs so Ps cannot prove reliance on Ds warranties anyway. Ds Omni SJ Brf.:18. However, the Court notes that Ds contradict themselves:

> "These documents and sources [upon which TPP formulary-creating agents rely in choosing drugs for their formularies] include medical and clinical evidence from the **literature**, relevant patient utilization and experience, economic data, provider recommendations, **FDA-approved package inserts, the product label, published data from clinical trials**, and relevant patient experiences".

Ds Omni SOMF:¶122. [emphasis added]. Contrary to Ds assertion in their Omni SJ brief, the bolded items may indeed constitute Ds "statements" upon which the TPP formulary-creating agents could and did rely.

Ps deny there was no reliance and assert if TPP formulary-creating agents had never gotten statements from Ds that expressed equivalence of the VCDs with the RLD, then those agents would never have included the VCDs in their formularies. Ps Opp. SOMF:¶¶83-86, 119). The Court finds whether Ps relied on Ds warranties to be a genuine dispute of material fact.

Accordingly, on the issue of Ps reliance on Ds express warranties, the Court **DENIES** defendants' Omnibus motion (Doc. No. 2562) and plaintiffs' motion (Doc. No. 2569) for summary judgment.

7.0 Violation of State Consumer Protection Laws ["CPLs"]

The certified TPP CPL Subclass a consists of the following states, where no showing of intent is required to prove deception: Alaska, Arizona, California, Connecticut, Florida, Louisiana, Missouri, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, and Washington.

7.1 Ps Arguments

Ps seek summary judgment of Ds violation of CPLs in the jurisdictions above and state , states the elements of a CPL claim (Ps SJ Brf:26):

1) defendant engaged in conduct proscribed by the act;
2) and which occurred in commerce; and
3) because of the proscribed conduct, plaintiff suffered injury and damages.

Ps clarify no state in this subclass requires intent to prove a CPL claim.

As for element 1, Ps assert that all jurisdictions in CPL subclass a have standardized language that generally proscribes "deceptive" OR "unfair" conduct. Table 4 shows what jurisdictions do or not rely on Federal Trade Commission Act ["FTCA"] guidance to define "deception" .

Table 4. CPL Subclass a Jurisdictions That Do or Not Rely on FTCA Guidance to Define "Deception"

CPL Subclass Group a Jurisdictions	
FTCA guidance for "deception"	**Non-FTCA guidance for "deception"**
Alaska, Arizona, California, Connecticut, Florida, Louisiana, New Hampshire, New York, North Carolina, North Dakota,[46] Oklahoma, and Washington	Missouri, Nebraska, Oklahoma, Oregon, and Pennsylvania

7.1.1 "Deception" in Jurisdictions relying on FTCA guidance

Ps SJ Brf: 26-30 states that under FTCA guidance "deception" must be a material misrepresentation likely to mislead a customer acting reasonably under the circumstances, and such misleading misrepresentations include false representations, sales of systematically defective products, and failure to meet warranty obligations. All three kinds of deception Ps assert occurred in this case. They allege substantially similar facts as they did for the breach of warranty claim: that Ds falsely represented their VCDs met cGMPs and compendial standards and were FDA-approved, generic versions of the RLD, hence FDA-classified therapeutic equivalents. ZHP SOMF:¶10, 10.5, 12, 52, 126-134, 145-154.5; Teva SOMF:¶¶37-40; Torrent SOMF:¶¶32-37.

Ps also aver that, after FDA disclosure in July 2018, each D publicly stated that their VCDs had presented an "unacceptable carcinogenic risk." ZHP SOMF: ¶¶ 143, 155; Torrent SOMF:¶¶ 21, 47-49; *see also* Teva SOMF:¶ 102. Ps imply that Ds had some inkling that their

[46] Plaintiffs do not pursue an "unfair" practices claim under North Dakota's *Unfair Trade Practices Law, N.D. Code § 51-10-01 et seq.* because the statute does not provide a private right of action. *Trade 'N Post, L.L.C. v. World Duty Free Americas, Inc.*, 628 N.W.2d 707, 710 (N.D. 2001). Plaintiffs' "deceptive" acts claim is made pursuant to North Dakota's *Unlawful Sales or Advertising Practices Act, N.D. Code § 51-15-01 et seq.*

previous statements (before FDA notice) of VCD purity and safety were deceptive. By Nov 2018, months after the recall, the FDA determined Ds VCDs were adulterated as a direct result of significant CGMP violations.

Ps assert these facts establish that Ds "deceived" in all Table 4 jurisdictions that follow FTCA guidance. Ds made material misrepresentations likely to mislead TPP agents who were considering whether to include VCDs in their formularies. In short, Ds deceived by warranting the near identity and therapeutic equivalence of the VCDS with the RLD, by not disclosing the contamination, and by systematically selling defective, i.e., adulterated, generic drug products.

7.1.2 "Unfair" Conduct in Jurisdictions Relying on FTCA guidance

Ps SJ Brf: 31-34 asserts the Third Circuit has dissected the FTCA's "unfairness" definition into 3 prongs: (1) substantiality of the injury; (2) whether countervailing benefits outweigh the injury; and (3) whether [plaintiffs] could have reasonably avoided the injury (*F.T.C. v. Wyndham Worldwide Corp.*, 799 F.3d 236 at 243-247) and decoded the FTCA to mean defendant's conduct may be adjudicated as both "deceptive" and "unfair" on the same facts. *Id.* at 245 & n.4. Although Ds arguments imply all three prongs must be shown to reach a finding of unfairness (Ds Opp. Brf:33-34), the U.S. Supreme Court has treated these prongs as disjunctive, not additive.[47]

Even though the elements of the express warranty claim and the CPL claim differ, Ps seek summary judgment on the same essential facts as asserted for the warranty claim. They aver these facts prove that Ds not only deceived TPPs but were also unfair to them. In particular, they aver that Ds VCDs were adulterated before the recalls because of the nitrosamine contamination caused by Ds non-compliance with required cGMPs and compendial standards. ZHP SOMF:¶¶ 33-34, 52, 61-62, 73, 86, 98, 115, 126-163.2, 165, 167, 170; Teva SOMF:¶¶ 8-25, 103-108; Torrent SOMF:¶¶ 23-24, 24(a), 24(b), 47-48, 53.

Ps also rely on this Court's Class Cert. Op. for the reason why contamination occurred.[48]

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[47] "[T]he Supreme Court implicitly approved these factors, apparently acknowledging their applicability to contexts other than cigarette advertising and labeling. [*FTC v.] Sperry [& Hutchinson Co.]*, 405 U.S. [233] at 244 n. 5, 92 S.Ct. 898. The Court also held that, under the policy statement, the **FTC could deem a practice unfair based on the third prong—substantial consumer injury—without finding that at least one of the other two prongs was also satisfied.** *Id.*" *Wyndham*, 799 F.3d at 243. [emphasis added].

[48] In Class Cert. Op. Doc. No. 2261 , this Court stated:

> "Defendants may be hard pressed to refute that their conduct resulted in nitrosamine contamination of VCDs; it's incontrovertible that the FDA recalled lots and batches of presumed-contaminated VCDs for several years. It is further incontrovertible in the morass of factual and legal arguments here that the contamination resulted from defendants' non-compliance of cGMPs at some level. Since defendants'

However, Ps reliance inflates the Court's meaning. This Court made the statement in fn. 48 not to prove any claim against Ds, but to emphasize that, rather than requiring a particularized showing from individual plaintiffs, the proposed subclasses all had the same preponderance of evidence that could prove their claims.

Ps assert Ds U.S. sales of millions of adulterated pills satisfy the prong to demonstrate a substantial injury for which, Ps aver, there was no countervailing benefit. Ds counter that the TPPs insureds received therapeutic benefit, which reduces TPPs economic injury.

Ps also aver they could not have reasonably avoided the injury. To press this point home, Ps argue Ds themselves assert their lack of knowledge of the contamination before FDA disclosure. Therefore, how much less likely were TPPs to know of the contamination and be able to avoid it. Ps conclude all elements of the FTCA standard to show Ds conduct was "unfair' have been met for those CPL Subclass a states relying on FTCA guidance.

7.1.3 " Deceptive"/"Unfair" Conduct in Jurisdictions Not Relying on FTCA guidance

Even though Missouri, Nebraska, Oklahoma, Oregon, and Pennsylvania do not rely on FTCA guidance in defining deception or unfair conduct, Ps assert the same evidence and analysis as discussed in Section 7.1.2 *supra* show deception or unfair conduct in these states. Although Ps generally cite caselaw that support their proposition, the Court notes Ps citation to Pennsylvania caselaw relates to a strict liability standard. The Court provides Pennsylvania jurisprudence in the fn. 49[49] in order to confirm Pennsylvania law supports the asserted result.

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conduct in making contaminated VCDs and in putting these into the U.S. drug supply chain, which plaintiffs paid for, is incontrovertible, that singular fact grounds all of plaintiffs' claims." *Id.* at 21.

[49] The Pennsylvania Supreme Court in *Commonwealth by Shapiro v. Golden Gate National Senior Care LLC*, 194 A.3d 1010 (Pa. Sup. Ct. 2018) defined the PA CPL standard:

> "The UTPCPL was created to even the bargaining power between consumers and sellers in commercial transactions, and to promote that objective, it aims to protect the consumers of the Commonwealth against fraud and unfair or deceptive business practices. [citation omitted]. As a remedial statute, it is to be construed liberally to effectuate that goal.[citation omitted] 'An act or a practice is deceptive or unfair if it has the capacity or tendency to deceive[,]" and "[n]either the intention to deceive nor actual deception must be proved; rather, it need only be shown that the acts and practices are capable of being interpreted in a misleading way.' *Commonwealth ex rel. Corbett v. Peoples Benefit Servs., Inc.*, 923 A.2d 1230, 1236 (Pa. Commw. 2007)". *Id*. at 1023

The *Golden Gate* Court clarified that the PA CPL prohibits more than mere deceptive advertising; it proscribes misrepresentation of a good, service and any other fraudulent/deceptive conduct likely to cause confusion or misunderstanding. *Id.* at 1028. The *Golden Gate* Court held who has standing to sue under the PA CPL is broad indeed and:

> "encapsulates those whose interests were affected by the enjoined conduct, i.e., those who lost money or property because of the enjoinable conduct that was found to violate the UTPCPL. This expansive definition, which is broader than the statutorily-defined term 'person,' furthers the long-recognized directive that the UTPCPL be construed liberally to achieve its objective of preventing fraud or unfair or deceptive business practices and leveling the playing field between businesses and consumers." *Id*. at 1034.

Considering *Golden Gate*'s guidance that the PA CPL is to be construed liberally, this Court finds succeeding on such a claim is

7.2 Ds Opposition to the CPL Claim

7.2.1 Substantive

Ds dispute the same facts they do for the breach of express warranty claim. Ds Opp. Brf. 37-43 argues, as for the breach of warranty claim, that Ds complied with all cGMPs and compendial standards and therefore their VCDs sold before FDA disclosure were not adulterated. Also, in their individual briefs, ZHP, Teva, and Torrent each assert Ps cannot prove the VCDs were adulterated. ZHP SJ Brf:6, Teva SJ Brf:4-6; Torrent SJ Brf: 8-9[50].

Ds argue again that Ps have not met their burden of showing non-compliance with cGMPs and that all of Ps arguments depend on the same evidence put forth for the express warranty claim. As Ps have failed to show that Ds engaged in the necessary elements of a CPL violation, Ds can have made no deceptive or unfair representations or omissions about their VCDs that invoke a CPL violation. For completeness, Ds aver, even if they did make such misrepresentations/omissions, the VCDs provided the therapeutic benefit of lowering blood pressure, which reduces Ps damages and imply any misrepresentations cannot have been material or unfair. Ds Opp.Brf:41.

Finding that the parties raise again the same genuine disputes of material fact whether VCD adulteration and compliance with cGMPs/compendial standards before FDA disclosure shows Ds liability for CPL violations, the Court acknowledges both parties have advanced the same evidence for the CPL claim as for the breach of warranty claim. As discussed *supra*, the Court has already found adulteration to be a genuinely disputed, material fact and a question for the fact-finder. That the parties dispute here over the same material facts suffices for the Court to find the CPL claim to be an issue for the fact-finder.

7.2.2 Procedural

Asserting in their Omni SJ Brief:22-23 that Ps CPL claims in certain jurisdictions are procedurally defective, Ds seek summary judgment on those claims in: District of Columbia, Hawaii, Louisiana, **Missour**i, Montana, and Ohio. The Court notes none of these jurisdictions, except Missouri, is in the relevant CPL subclass a[51] but finds that the District of Columbia, Hawaii, Louisiana, Montana, and Ohio are jurisdictions in the TPP Common Law Fraud Claim

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a fact-intensive exercise.

[50] ZHP in its Opp. Brf. directly addresses only the fraud claim and seeks summary judgment on the issue of adulteration. Torrents Opp. Brf. similarly addresses only the fraud claim but also asserts and points to evidence that Torrent made no material misrepresentation but does not affirmatively argue evidence specific to the CPL claim. Teva filed no opposition brief.

[51] To reiterate, TPL subclass a includes the following: Alaska, Arizona, California, Connecticut, Florida, Louisiana, **Missouri**, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, and Washington.

Group c, where the scienter standard is the highest. As a CPL claim requires deceptive or unfair conduct that can amount to a material misrepresentation or omission likely to mislead but does not require the defendant's knowledge or intent that the misrepresentation will mislead, violation of consumer protection laws, while often termed "consumer fraud", need not rise to the level of fraud. Consequently, the Court regards Ds inclusion of District of Columbia, Hawaii, Louisiana, Montana, and Ohio in the CPL discussion as inappropriate.

As for the relevant Missouri CPL, plaintiffs who purchase products for commercial purposes have no standing to sue under the *Merchandising Practices Act ["MMPA"]*, Mo. Rev. Stat. §§ 407.025.1. The Court in *In re Express Scripts, Inc., Pharmacy Benefits Mgmt. Litig.*, MDL 1672, 006 WL 2632328 (E.D. Mo. Sept. 13, 2006) defined "purchase" to mean "obtaining by paying money or its equivalent" and held that a PBA Plan that purchased services for its client police officers lacked standing. These services were not purchased for the Plan's personal, family, or household purposes as required by the statute, but for a business purpose, i.e., to serve the Plan's clients. *Id*. at *10. The Court finds that the TPPs do not have standing to sue under the Missouri CPL *Merchandising Practices Act ["MMPA"]*, Mo. Rev. Stat. §§ 407.025.1.

Ds Opp. Brf:36-37 also asserts other procedural deficiencies in Ps CPL claims, namely:
-different jurisdictions have CPL laws that assert different definitions and conditions of the required elements—deceptive or unfair conduct and specifically, some states apply lesser standards of evidence while others apply higher standards.
-those jurisdictions that Ps assert follow FTCA guidance are not bound by that guidance, implying the FTCA standards in those states are actually not uniform, but variable;
- North Carolina and Pennsylvania require reliance on the deception, fraud, or unfair representation;
-Ps have not articulated CPL standards in those jurisdictions that do not follow FTCA guidance.

Ps Rep.Brf:14-17 counters that:
-Ds have overstated the variability in CPL standards in FTCA jurisdiction and to some extent have mischaracterized differences;
-Ds assertion that certain jurisdictions following FTCA guidance actually have not done so is unsupported by caselaw;
- Ps cite caselaw supporting their proposition that both North Carolina and Pennsylvania do not require reliance.

The parties also dispute the correctly defined standards of the CPL subclass a jurisdictions. From one perspective, disputes over legal standards are but another kind of genuine dispute over material facts. That is, such disputes ask the question: what facts are required to prove a CPL claim. Put differently, what facts are needed to show whether the

VCDs were adulterated before FDA disclosure in order to prove a CPL claim. The Court finds that Ps have cited correct, supporting caselaw of the standards in TPP CPL subclass a, with the exception of Missouri.

7.3 Resolution on the CPL claim

Accordingly, that the parties raise a genuine dispute about the same material facts as for the breach of warranty claim, on the issue of violation of Consumer Protection Statutes, the Court **DENIES** plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569).

The Court also **DENIES** defendants' Omnibus motion (Doc. 2562) and Teva's motion (Doc. No. 2565) for summary judgment on the issue of violation of Consumer Protection Laws, **EXCEPT** the Court **GRANTS** defendants' Omnibus motion (Doc. 2562) and Teva's motion (Doc. No. 2565) for summary judgment for violation of Consumer Protection Laws in Missouri.

8.0 Common Law Fraud Claim

The certified Common Law Fraud Subclass TPP Group c constitutes those jurisdictions where the scienter standard is the highest: Alaska, Arkansas, Colorado, District of Columbia, Florida, Idaho, Iowa, Louisiana, Massachusetts, Minnesota, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wyoming, and Puerto Rico.

Ps seek two summary judgment motions on their common law fraud claim: against ZHP (Ps SJ Brf-ZHP, Doc. 2569-2) and against Torrent (Ps SJ Brf-Torrent, Doc. 2559-1). Relying on New Jersey law as representative of the laws of the jurisdictions in this subclass, Ps assert the five elements of common-law fraud are:

1) material misrepresentation of a presently existing or past fact;

2) Ds knowledge or belief of the false fact;

3) intent that the other person rely on it;

4) the other person's reasonable reliance on the false fact;

5) resulting damages.

Ds (Omni SJ Brf.Doc. No. 2562-1:18-22 and Opp. Brf., Doc. No. 2603) seek summary judgment that Ps common law fraud claims fail because Ps can neither establish that Ds made any false or deceptive statement or omission nor satisfy the reliance requirement of this claim.

8.1 ZHP

8.1.1 Ps Arguments

Regarding ZHP, Ps marshal facts to show ZHP knew of the presence of NDMA in its API and consequently in its finished dose VCDs by at least 27 Jul 2017. Their evidence is an email sent by Dr. Lin, Jinsheng, a PhD chemist who worked at a ZHP wholly-owned subsidiary where he reviewed degradation products in ZHPs manufacturing processes. On 27 July 2017, Dr. Lin sent an email to several ZHP top management officers and personnel, including heads of quality, risk assessment, board members and to Li, Min , ZHP Vice President for ZHP Analytical Operations[52], informing them of the nitrosamine contamination of irbesartan API, a related sartan.

More importantly, Dr. Lin's email states such contamination had already been known for valsartan API. Ps SOMF:40-42. The email provides no further details about the nitrosamine contamination of valsartan API, except for its known existence. ZHP SOMF¶163.2. But Ps state that the 27 Jul email actually describes the root cause of the contamination: sodium nitrite quenching of sodium azide and the need to optimize the sodium azide quenching step in the manufacturing process. The email also points out that the sodium azide quenching step was known to be a common problem in the manufacture of a related sartan, irbesartan. (Contamination of Irbesartan with NDMA is also complained of, in a separate section of this MDL). Ps SJ Brf.-ZHP, Doc. 2569-2:6.

Ps fraud claim against ZHP is that from 27 Jul 2017 until 17 Jul 2018 when it voluntarily recalled its VCDs as valsartan, ZHP made a continuing material misrepresentation by the very act of selling contaminated API and VCDs, which was that its VCDs were FDA approved valsartan and compliant with all required cGMPs and compendial standards. Further, knowing they were making that continuing material misrepresentation of VCD purity, quality and equivalence with the RLD, ZHP never notified either their customers or the FDA of the contamination during this period. Ps SOMF:41. Ps aver that is fraud. Ps SJ Brf.-ZHP, Doc. 2569-2:4-7.

Regarding ZHPs intention that TPPs rely on the misrepresentations, P argue that is indisputable. *Id:* 8. Since ZHP knew of the VCD contamination and nonetheless continued selling its contaminated VCDs until the VCDs recall, Ps state that ZHP not only had scienter but its continued sales and silence about the contamination shows its intent to continue driving fraudulent sales. *Id.:* 7. Even ZHPs corporate representatives acknowledged that if ZHP had knowingly sold contaminated VCDs, that would be unacceptable and unethical. *Id:* 8; ZHP

[52] Dr. Li, Min holds a PhD in organic chemistry from John Hopkins University in Baltimore, MD.

SOMF:¶163.5. Importantly, there is no evidence demonstrating that ZHP ever investigated the possibility of contamination of its valsartan API after 27 Jul 2017 until June 2018 when one of its customers notified ZHP that it had found NDMA in the API.

As for TPPs reliance on ZHPs misrepresentation, as they did for the express warranty claim, Ps aver that, until ZHP itself, the FDA, the EMA or a ZHP customer revealed the nitrosamine contamination, no TPP would or could have known of it. The only pathway to disrupt TPPs reliance was the direct disclosure of the nitrosamine contamination in a way that resounded throughout the medical community, i.e., a voluntary recall. Ps SJ Brf.:8. Finally, Ps aver TPPs were damaged by paying for VCDs that were adulterated and therefore worthless.

As for the level of nitrosamine contamination, on 2 Sep 2018, Dr. Li, VP of ZHP Analytical Operations, confirmed to the FDA that ZHPs own testing of a large sampling of its API batches showed each batch exceeded the NDMA limit set by the FDA. Ps SOMF:¶31.

Ps aver that ZHPs knowing commission of fraud resulted in TPPs paying for contaminated VCDs, which they would not have done so, had the TPPs known of the contamination. Ps SJ Brf.: 8.

8.1.2 ZHP Arguments

ZHP counters all of Ps arguments. First, SJ Brf., Doc. 2564-1:6 argues that the FDA never declared VCDs marketed and sold by Prinston d/b/a Solco were misbranded, misrepresented or adulterated. Therefore, the VCDs sold by Solco could not be deemed adulterated before the FDA disclosure in July 2018. Given that ZHP argued that the Chinese parent and Huahai U.S. did not sell VCDs in the U.S., the ZHP SJ Brf. is silent about the adulteration of ZHPs API. Other of ZHPs arguments are:

-That in the summer 2018, the FDA issued statements that declared the presence of NDMA in ZHPs manufacturing process was "unexpected". *Id.*:5 relying on ZHP SOMF:¶¶61-63;

-That Dr. Ramin Najafi, one of Ps organic chemistry experts, testified in his deposition that a generic drug could be bioequivalent to the RLD even while that drug's impurity profile differed. ZHP SJ Brf., Doc. 2564-1:3.

-To evidence bioequivalence of the contaminated VCDs, ZHPs quote testimony of their pharmaceutical expert, Dr. Michael Bottorff, that the contaminated VCDs function in the body to lower blood pressure similarly as uncontaminated valsartan. *Ibid.*

-As for misrepresentations, ZHP avers that neither ZHP China or Huahai U.S. made any to TPPs. *Id.*:5.

-ZHP states the record is devoid of any showing that TPPs relied on ZHPs statements about its VCDs, which begs the question of an assertion of fraud.

-As for the contents of the 27 Jul 2017 email, ZHP cites a case that one email does not a record of fraud make as a matter of law.[53]

8.2 Torrents Arguments

As for Torrents fraud, Ps SJ motion-Torrent, Doc. No.2559-1:2 argues that ZHP notified Torrent of the nitrosamine contamination on 3 Aug. 2018. After that notice Torrent did start working with the FDA for a recall but did not stop selling VCDs for two weeks, until 17 Aug 2018, even though customers had directly asked Torrent if the VCDs were contaminated. It is for this two week period that Ps specifically claim Torrent is liable for fraud because Ps aver Torrent's scienter of VCD contamination is indisputable. *Id*. at 3-4.

Ps also aver, as with ZHP and Teva, that Torrent had not complied with required cGMPs and compendial standards to ensure that its VCDs had the safety and purity profile of the RLD. Ps state all of the VCDs Torrent sold in the U.S. were nitrosamine-contaminated. They further aver that Torrent, like Teva, turned a blind eye to ensuring that it was complying with its quality and risk assessment procedures. Ps aver that both Teva and Torrent did so because of the low cost of the ZHP API. Ps also argue the low cost of ZHP API incentivized Torrent to have its customers rely on its misrepresentations in those two weeks while it continued to sell its VCDs. Ps aver as before that TPPs reliance is a matter of law as the TPPs could do nothing else but rely on Ds misrepresentations of the purity and safety of their VCDS. *Id*. at 5.

Torrent seeks summary judgment on Ps fraud claims, asserting in their SJ Brf. (Doc. No. 2570:3-9) and Opp. Brf. (Doc. No. 2595:3-10):

-Torrents VCDs were not adulterated because the FDA never declared Tevas VCDs to be adulterated.

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[53] Ds cited case, *Tershakovec v. Ford Motor Co.*, 546 F.Supp.3d 134, 1364-65 is irrelevant.

The T*ershakovec* email was from a **single unverified consumer report** with no diagnostic information about the car's computer system failure. The court rightly found this to be insufficient evidence from which a reasonable juror could find ***Ford had knowledge*** that the relevant car models went into an unsafe mode of driving when using the cars on race tracks. Ds cite that the 11th Cir. (49 F.4th 1299 (11th Cir. 2023)) affirmed the district court's holding of insufficient evidence. This is incorrect. The appeal related to the district court's class certification opinion and in that context, the 11th Circuit remanded back to the district the issue of reliance on fraud in California and other jurisdictions. *Id.* at 1316.

Tershakovec is irrelevant because here ZHP was internally notified by its own, reputable ZHP chemist to ZHPs upper management of a specific problem with the sodium nitrite quenching process, which aided the formation of nitrosamines in the resultant API. The Court sees that there is **sufficient, clear, specific** information **from ZHP to ZHP** to let a reasonable juror determine if ZHP knew of the contamination because of the 27 Jul 2017 email.

-and it is only the FDA that can make such a determination.

-therefore Ps can show no evidence of Torrent's material misrepresentation or

- evidence that Torrent acted with intent to have others rely on the misrepresentations

-As Torrent did not and could not make a misrepresentation about its VCDs, Ps cannot show Torrent acted with scienter.

- therefore, Ps fraud claim fails for lack of Torrent's scienter.

-consequently, Ps cannot recover punitive damages.

In countering Ps arguments, Torrent disputes Ps assertion that Torrent did no or inadequate testing for the purity and safety of the VCDs. Rather the record shows Torrent conducted independent specification testing of every batch of API from ZHP in line with cGMPs, compendial standards and industry standards. Torrent Opp.SOMF, Doc. No. 2597: ¶9. Torrent makes the point that when the valsartan ANDAs were approved by the FDA, and up through recalls in July 2018, there was no compendial standard for testing for nitrosamine impurities in VCDs. *Id.*: ¶10.

The Court observes that to a large extent, parties are speaking past each other, when Ps assert Ds did insufficient testing and Ds say they did exactly those tests required **of the industry at the time**. This is because the industry standards of testing, including even cGMPs and compendial standards, did not particularly identify refined and more difficult test methods needed to detect NDMA. Whether Ds could have discovered or should have been searching for nitrosamines before FDA disclosure in July 2018 or developing more refined testing is a question for the fact-finder.

Nonetheless, Torrent marshals evidence to show it had tested VCDs and complied with the testing standards at the time. *Id.*:¶¶12-13, 50, 53. Torrent specifically disputes that it took no action to develop tests for VCD contamination in the two-week period in August 2018 that Ps aver Torrent continued to sell VCDs knowing they were contaminated. *Id.*: ¶¶21-22.

As for its alleged misrepresentations, Torrent declares that Ps have misstated the deposition testimony of an important 30(b)(6) deponent, Mr. Sushil Jaiswal Head of Torrent's Quality department, who stated that post recall the tested-for NDMA amounts in Torrents VCDs were below the FDA reporting thresholds. Therefore, Torrent made no misrepresentations by not disclosing its VCDs were adulterated. *Id.*:¶¶23-24.

And as for Ps averment of Torrent's fraud between 3 Aug 2018 and 17 Aug 2018, Torrent disputes it made any false statements to its customers. In particular, Torrent stated it was investigating whether its VCDs were contaminated. *Id.*:41.

8.3 Tevas Arguments

Ps did not file a separate summary judgment motion for fraud against Teva but did plead fraud against all Ds in the Third Amended Complaint. However, Teva did file a separate motion seeking summary judgment on Ps fraud claim.

Teva seeks summary judgment not only on all three claims— breach of express warranty, violation of CPLs, and common law fraud (Tevas SJ Brief, Doc. 2565-1), but also on issues:

1) that the Court lacks personal jurisdiction over Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") on the TPP Trial claims. (The parties' stipulation mooted this issue. *See also* fn. 16).

2) that Teva's VCDs were not adulterated as a matter of law. (The Court has already ruled *supra* that adulteration of VCDs raises a genuine dispute of material fact);

3) Since Ps have presented no evidence Teva acted with the requisite scienter, Ps fraud claim fails; and

4) Ps have presented no evidence to support recovery of punitive/exemplary damages against Teva, which the Court discusses in Section 9.5.

In opposition, Ps declare Teva purposefully played the ostrich when it did not do the needed diligence to affirm the quality of ZHPs API, that is, when it did not comply with its own standards of quality assurance and risk assessment. Ps SOMF-Teva, Doc. No. 2566:¶¶1-5, 42-55. Ps assert Teva misrepresented the quality of ZHPs manufacturing changes in its own internal standards of quality operations by recording them as minimal. But, according to Tevas own operating procedures, ZHPs changes were actually deemed moderate and called for a more refined review. *Id.*:¶¶ 56-60. Teva purchased contaminated API from ZHP for years but never fully or appropriately tested the API independently. *Id.*:¶¶ 61-65. However, finding serious ZHP cGMP violations in certain audits of ZHPs manufacturing reports from 2012,2015, and 2018, Ps aver Teva should have executed the appropriate gas chromatography testing for nitrosamine contamination in the API according to Tevas own cGMPs, but didn't. *Id.*:¶¶ 66-67. Nor did Teva follow up with ZHP to get a full and proper description of the FDAs site inspection of the Chinese API manufacturing facility in May 2017 in which the FDA had found cGMP violations by ZHP. *Id.*:¶¶ 71-73. Ps assert Tevas many failures over the years to follow through and comply with its own internal operating procedures for quality strongly shows Teva failed its legal duty to investigate its own suspicions about the possible contamination. Because of that failure, Teva materially misrepresented their own VCDs had the safety and purity profile of the RLD.

Teva asserts there was no duty and moreover they did not fail to meet it because they complied with all industry standards. Tevas SJ Brf.:2-3, Tevas SOMF:¶ 96. Adequate testing

for nitrosamines in pharmaceuticals was not developed until after the recall. Ds OMNI Opp. SOMF, Doc. No. 2571:¶¶62-3, Tevas Opp. SOMF, Doc. No. 2602:¶¶18-21, 67-76, 96-100. Moreover, Teva could not have known to test for nitrosamines in the VCDs as before recall there was little to no understanding in the chemical literature to anticipate that ZHPs changed chemical processes would result in such contamination. *Id.*:¶ 64. Further, Teva asserts it cannot have breached a non-existent duty because Tevas manufacturing facilities had received good cGMPs ratings from federal regulators. Tevas SJ Brf., Doc. No. 2565-1:2 Consequently, it could not have known to even anticipate such a duty by testing the VCDs for nitrosamine contamination. Teva Opp. SOMF, Doc. No. 2602:¶ 60. Further, Teva asserts it performed specification testing of all valsartan API from ZHP both before and after ZHP changed its manufacturing processes and confirmed every batch received from ZHP met all applicable specifications.[54] *Id.*:¶51. Tevas declares it had no legal duty to investigate discrepancies in ZHPs reports other than to do the specification testing, which it did. *Id.*:¶¶ 26, 66.Teva declares they can have made no material misrepresentation about their VCDs.

As for their fraud claim, Ps argue Teva made a material misrepresentation that the quality and purity of their VCDs was equivalent to the RLD when their VCDs were adulterated for lack of proper diligence in complying with oversight cGMPs. Ps infer that Teva must have suspected contamination of ZHP API and did not test for it and/or reneged on its own quality and risk assessment procedures in order to purposefully avoid knowing if the VCDs were contaminated. Ps Rep. Brf.:1-2. Ps aver that Teva's material misrepresentation and scienter are inferred from the same evidence and supported by the assertion Tevas VCDs were adulterated because of Tevas knowing non-compliance with its own quality and safety procedures that incorporated required GMPs and compendial standards.

This is not the same quality of scienter that Ps argue for either ZHP or Torrent, where Ps provide purported, more-or-less direct evidence that ZHP and Torrent knew their VCDs contained nitrosamines for some period before FDA disclosure. Although Ps do not cite a specific document that conveys Tevas knowledge, Ps evidence from several incidents over the years of Tevas non-compliance with its own safety standards implies a pattern of Tevas not seeking such knowledge and raises a question.

8.4 Resolution of the Fraud Issue

As the Court has ruled *supra* that the adulteration of the VCDs is a question for the fact-

[54] To be clear, that Teva did "specification testing" of ZHPs API is tantamount to Tevas assertion that it did the kind of testing that complied with the industry standard. "Specification testing" did not contemplate using gas chromatography to test why there were unknown peaks in ZHPs API, which turned out to be NDMA.

finder, for Ps fraud claim, the principal question is whether Ps have proved as a matter of law the required elements, namely,

that each of ZHP, Teva, and Torrent misrepresented their VCDs had the same safety and quality profile as the Orange Book formulation when each Ds lack of compliance with cGMPs and compendial standards may or not have signified the VCDs were adulterated,

that each D knew they were misrepresenting the VCDs, and

and intended the TPPs to rely on that misrepresentation, and

that the TPPs did so rely.

Of greatest importance for this claim is whether the Court finds that Ps have or not proved another Ds scienter in making a misrepresentation or omission, which is the key element to a finding of fraud as a matter of law. The Court finds there are too many genuinely disputed, material facts to show or not whether Ds knowingly or intentionally misrepresented their VCDs.

Accordingly, the Court **DENIES** on the issue of fraud:

Ds Omni motion for summary judgment (Doc. No. 2562);

ZHPs motion for summary judgment (Doc. No. 2564);

Tevas motion for summary judgment (Doc. No. 2565);

Torrents motion for summary judgment (Doc. No. 2570);

Ps motion for summary judgment against ZHP (Doc. No. 2569); and

Ps motion for summary judgment against Torrent (Doc. No. 2559).

9.0 Issues Related to Whether Damages are Owed and the Method of Calculating Them

In addition to the three claims of express warranty breach, violation of consumer protection statutes, and common law fraud, Ds Omni SJ Brf., Doc. No. 2562 seeks summary judgment on various issues relating to TPPs damages.

9.1 Plaintiffs Have No Cognizable Injury

Ds Omni SJ Brf. (Doc. No. 2562-1:24-27) argues that, since TPPS cannot establish a cognizable injury, the Court should grant Ds summary judgment on this issue. Ds assert TPPs can not have experienced an economic loss for reimbursing their insured's VCDs because their insureds received VCDs that performed as marketed, that is, lowered blood pressure. Since consumers got what they paid for—an effective hypertensive medicament—TPPs, as the consumers' insurers, can assert no economic loss in reimbursing for an effective product.

In opposing Ds argument, Ps assert a damages theory in which TPPs are owed the full extent of their economic loss because the VCDs were worthless. Ps economic expert, Dr. Rena Conti, postulates that, had the FDA known of the nitrosamine contamination, the contaminated VCDs could have been unavailable for sale in the U.S. market. Thus, had the FDA known, the contaminated VCDs would have been unmerchantable and therefore lacked a supply curve, leaving them worthless economically. Thus, Ps declare the VCDs were unmerchantable and worthless from when they first entered the U.S. market. TPPs are owed the full amount they paid for worthless VCDs for years.

Ds have repeatedly sought the Court to repudiate Ps worthlessness theory: at the motion to dismiss stage, at the class certification stage, and recently in a motion to decertify the certified classes. In their Omnibus motion for summary judgment, Ds have propounded the theory that, since the FDA never officially deemed the VCDs adulterated under Federal statute until months after the first recall in July 2018, those VCDs that were sold **before being characterized** as adulterated in November 2018 were legally merchantable, even if contaminated. Ds merchantable theory is based on evidence showing that the VCDs, regardless of the nitrosamine contamination, functioned as expected to lower consumers' blood pressure and similarly as uncontaminated valsartan. The VCDs thereby delivered a bargained-for exchange, which leaves the TPPs without a cognizable injury.

Ps characterize Ds no-cognizable-injury theory as a veiled lack-of-standing argument. That is, lacking an injury, TPPs have no standing to sue for the three claims. That the TPPs have proper standing—because this Court recognized their cognizable injury—was decided three years ago (*See* Doc. No. 728:8-15), from which decision the parties have advanced the litigation many times over.

Regardless of what this argument is called in the parties' summary judgment motions—Ds no-cognizable-injury or Ps lack-of-standing—these theories hinge on different legal perspectives and on genuinely disputed, material facts for the trial fact-finder. Pursuant to *Rule 56(a)*, the parties' arguments dispute a material fact about the amount of damages—from none to the full amount TPPs reimbursed for the insureds' scripts. Their damages arguments not only go to the very heart of the parties' liability, but depend on strenuously debated damages theories.

The parties' damages disputes hinge on—as do most of their arguments about Ds liability of the claims—whether the VCDs can be deemed adulterated, at what point were they adulterated, and what entity can make that determination. Given the utmost criticality of the definition and timing of drug adulteration in the TPP trial, the Court is constrained by *Rule 56* not to decide the issue of whether the TPPs are owed damages and leaves that for the fact-

finder.

As discussed *supra* in section 8.3, the Court reiterates that neither the U.S. Code on adulteration (*See* fn. 29) nor an accompanying Code of Federal Regulations[55] limits the determination of drug adulteration to only the FDA. To be clear, the Court holds that, just as fact-finders in U.S. federal district courts decide every day whether U.S. statutes and their accompanying Code of Federal Regulations have been violated, so too the TPP trial fact-finder here may weigh the parties' facts and arguments to decide whether the VCDs were adulterated.

The Court finds that neither Ds as movant nor Ps as non-movant have met their *Rule 56* burdens. There is a genuine dispute of material fact as to the amount of TPPs damages, which centers on whether the damages are nothing because the VCDs gave the TPPs what they paid for—lowered blood pressure—or the VCDs were economically worthless and TPPs are owed the full amount they paid for the drugs. The Court finds Ds arguments that TPPs have no cognizable injury and Ps opposition that the VCDs are worthless to hinge on the very central question of the VCDs adulteration and raise a genuine dispute of material fact for the fact-finder.

Accordingly, on the issues whether plaintiffs have no cognizable injury, whether they are owed damages and in what amount, the Court **DENIES** (Doc. No. 2562) defendants Omnibus motion for summary judgment.

9.2 That Ps Damages Model Cannot Establish Damages on a Class-wide Basis

Ds Omni SJ Brf. (Doc. No. 2562-1) seeks summary judgment on the issue that Ps model of calculating damages, which Dr. Rena Conti Ps economic expert has put forth, cannot actually compute the economic loss damages for the TPP subclasses. Ds argue that Ps model calculates TPP economic loss at the point of sale ["POS"] where the prescriptions were sold. This is because Ps POS model[56] is based on IQVIA Exponent data that captures POS drug sales information. Ds point out the POS model does not match this Court's decision[57] that TPPs injury occurred where TPPs were located and paid for the prescriptions, the Point of Payment ["POP"] model. Ds assert the POP model is the correct one for calculating Ps damages; and the POS model is useless and does not tally TPPs actual damages, because of the mismatch

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[55] **§ 314.170 Adulteration and misbranding of an approved drug.**
All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act. FDA is authorized to regulate approved new drugs by regulations issued through informal rulemaking under sections 501, 502, and 503 of the act.

[56] Upon which the jurisdictions for Ps classes and subclasses were certified.

[57] MTD Opinion 2, Doc. No. 728.

between the POS jurisdictions and the POP jurisdictions. Ps model of damages calculation being futile, Ds argue Ps can seek no proper damages.

The Court observes Ds argument raises an intertwined attack on the traceability and ascertainability of Ps economic model of calculating their damages. On traceability, the Court reminds the parties of its reconsideration of its MTD Opinion 2 in its Opinion and Order RE Parties' Objections to Special Master Report and accompanying Special Master Order 46. We found there that:

> "Since *Back2Health Chiropractic Center, LLC v. Sentinel Insurance Company, Ltd.*, Civ. No. No. 20-6717 (JMV-MF) , 2021 WL 960875, at *6-*7 (D.N.J., 15 Mar 2021) explicitly backtracks from *Semeran* (a basis for the MTD Opinion 2), this Court finds it fitting to upgrade its ruling in the MTD Opinion 2 on the traceability requirement of named plaintiffs at the motion to dismiss stage" … "Thus, the Third Circuit found that two plaintiffs that were injured in Pennsylvania had standing to pursue claims **on behalf of a nationwide class of plaintiffs that were injured in other states**. *Back2Health Chiropractic Center*, 2021 WL 960875, at *6-7" [emphasis added]. Doc. No. 1994:9-10

Ds reliance on the standing-traceability arguments of this Court's Motion to Dismiss **Opinion 2** must yield to the Third Circuit's finding that even **at the motion to dismiss stage** putative class members could represent claims of plaintiffs injured in jurisdictions where they did not reside. This implies that calculating TPPs payouts in jurisdictions where the TPPs do not reside, which confirms that POS claims are traceable and therefore calculable under the Third Circuit jurisprudence on standing.

Ps argue that this Court defined the TPP subclasses, including the relevant ones here, as all TPPs that paid any amount of money in the specified states. They assert that wherever IQVIA Exponent data show TPPs paid for an insured's script, regardless if payment occurred in the TPPs POS jurisdiction or the TPPs POP jurisdiction, the POS model could accurately calculate TPP damages. The Court recognizes that, in order to accurately calculate TPP damages using IQVIA Exponent data, a translating mechanism is needed. Such a mechanism would avoid under-awarding and would de-duplicate any double awards (as when the TPP is in a subclass that includes both its POS and POP jurisdictions) because it would convert any particular TPP award in a POS jurisdiction to an award only in its POP jurisdiction.

Clearly, the MDL is way beyond the motion to dismiss stage but the finding of standing-traceability of MSP is unshaken by any argument the parties have raised and certainly not by Ds implied lack of ascertainability argument. Importantly, because of this Court's revision of the putative class members' traceability arguments, it is clear that this Court's standing

opinion defining POP locations does not work an impossibility to defining the ascertainability of the certified subclasses as the POS location.

Contrary to Ds implications that this mismatch engenders an unworkable calculation of TPP damages, the parties can make this work by developing a translating mechanism, such as a subroutine, to convert the TPPs Point of Sale [POS] data acquired from the gold-standard IQVIA data to the TPPs Point of Payment [POP] locations. The Third Circuit has found such translating mechanisms to demonstrate ascertainability.[58]

Accordingly, on the issue of whether Ps model of damages cannot establish damages on a class-wide basis, the Court **DENIES** defendants' Omnibus motion (Doc. No. 2562) for summary judgment.

9.3 That Plaintiffs Cannot Prove Defendants' Alleged Misrepresentation Proximately Caused TPP Injury

Ds SJ Brf. (Doc. No. 2562-1) seeks summary judgment on the issue that Ps cannot prove that Ds alleged misrepresentations, omissions or breached warranties caused TPPs damages because there are intervening causes, notably intervening actors in the drug supply chain whose conduct reduces TPPs losses. These actors include the physicians who prescribed the VCDs as well as the Pharmacy Benefit Managers and agents who developed the TPP drug formularies and included the VCDs there. Ds aver that calculating TPP damages would have to take into account each individual insureds' intervening causes in order to reduce damages appropriately to achieve an accurate amount.

For this argument that intervening causes necessarily reduce TPP losses, Ds rely on *Sargeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F.Supp. 3d 305 (E.D.N.Y. 2014). In *Sargeants*, the relevant claim was for violation of the federal RICO statute because of defendant Sanofi's alleged misrepresentations to physicians about the safety of its off-label drug.[59] However, establishing RICO causation in *Sargeants* required a wholly different legal standard than that for the claims here, which makes Ds "attenuated" theory based on

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[58] *See* this Court's Class Cert. Op., Doc. No 2261:26-27, reviewing the Third Circuit's findings in *RealPage:*
"While [a] linking task appears formidable, the *RealPage* Court has nonetheless made clear that, if the data exist to reasonably identify class members, then having to link disparate kinds of data to more accurately name all possible, putative members cannot be the reason to fail ascertainability".

[59] The *Sargeants* TPPs relied on generalized proof that the prescribing physicians relied on Sanofi's misrepresentations. They argued that, despite the presence of other factors in the causal chain, a sufficiently direct relationship may exist when plaintiff's injury is a foreseeable and natural consequence of defendant's misconduct. *Id.* at 316. The *Sargeants* Court discounted plaintiffs' argument and found that, for a RICO claim, specific proof of reliance is a required element to prove conspiracy and particularly needed was specific proof of Sanofi's misrepresentations to the prescribing physicians and their reliance on it in prescribing the off-label drug. The *Sargeants* Court held there was an unproven intervening cause that could not demonstrate a RICO conspiracy.

Sargeants irrelevant and why the Court finds *Sargeants* inapposite.

Ironically, in the Third Circuit, the Chief Judge of the Eastern District of Pennsylvania, considered the applicability of *Sargeants* in a case with facts quite similar to here. In *Blue Cross Blue Shield Association v. GlaxoSmithKline LLC*, 417 F.Supp.3d 351 (E.D. Pa. 2019), Judge Sánchez summarized his findings:

> Plaintiffs, 38 private health insurance companies that purchased billions of dollars' worth of adulterated pharmaceutical drugs from Defendant GlaxoSmithKline LLC (GSK), bring claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) and Pennsylvania law, alleging they purchased the drugs at issue based on GSK's misrepresentations that the drugs were manufactured in accordance with the Food and Drug Administration's "current Good Manufacturing Practices." [footnote omitted]. Plaintiffs claim the adulterated drugs were worthless and had they known of the adulteration, they would not have included the drugs in their formularies. GSK has moved for summary judgment as to all claims pursuant to *Federal Rule of Civil Procedure 56*. Because Plaintiffs' RICO (Counts I - III) and unjust enrichment (Count VII) claims fail as a matter of law, GSK's motion for summary judgment will be granted as to those claims. **[Defendant GSK's] motion will be denied as to Plaintiffs' remaining claims for fraud (Count IV),** civil insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117 (Count V), negligent misrepresentation (Count VI), **and breach of express warranty** (Count VIII), and breach of implied warranty of merchantability (Count IX), which present genuine issues of material fact for trial. *Id.* at 537. (emphasis added).

Plus, Judge Sánchez found defendant GSK's theory unavailing that certain intervening conditions necessarily reduced plaintiff TPP damages:

> "... [Defendant] GSK asserts Plaintiffs' claimed damages theory [which, like here, was also that the drugs at issue were economically worthless] is impermissibly speculative. GSK argues Plaintiffs cannot demand damages in the amount of the full price paid for the drugs because the calculation fails to take into account the cost of therapeutic alternatives Plaintiffs would have had to provide, as well as any rebates they may have received for covering the At-Issue Drugs. GSK relies on *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014), and *UFCW Local*

1776 v. Eli Lilly & Co., 620 F.3d 121 (2d Cir. 2010)."[60] *Blue Cross Blue Shield* ["BCBS"], 417 F.Supp.3d at 558.

In distinguishing *Sargeants* and *UFCW Local 1776*, the *BCBS* TPP plaintiffs clarified they had no option but to rely on Defendant GSK's statements about the safety of the Drug At Issue, which was used (not in an off-label application as in *Sargeants* but) directly for a medical condition. In using GSK's Drug At Issue in their formulary, the *BCBS* TPPs had only a yes/no option, not a nuanced choice, in relying on the drug's relative efficacy or expense, which translated into the *BCBS* TPPs blind reliance on GSK's misrepresentations about its Drug At Issue. *Id*. at 558-559. Judge Sánchez found the *BCBS* TPPs arguments compelling and completely disregarded *Sargeants* and *UFCW Local 1776*. So does this Court.

In addition to intervening causes affecting causation, Ds arguments also suggest that, for TPPs to have experienced loss by reimbursing the VCDs, their insureds had to have been injured, thereby revealing a supposedly, too-attenuated proximate cause. But, the insureds' injury is not at all the activating causation factor for TPPs economic loss. TPPs aver direct economic loss because they paid for drugs contaminated with a probable carcinogenic genotoxin, which Ps aver Ds knew they had not made safe or equivalent to the RLD. This is, as Ps aver, because of: Ds noncompliant cGMP testing when ZHP changed its manufacturing process; Ds wholly inadequate compliance with their own stated risk assessment and quality procedures set up to comply with cGMPs; and their silence to the FDA about the full extent of the chemical changes to ZHPs manufacturing processes of the API.

That TPPs could do little to verify independently Ds representations that the VCDs were cGMP compliant underscores why TPPs aver their reliance was foregone. Moreover, there is no dispute between the parties on why TPPs seek damages: that TPP damages arise from Ds non-compliance with cGMPS which resulted in nitrosamine-contaminated drugs sold in the U.S. market. The factual dispute among the parties is over how much the TPP loss was: whether full reimbursement, partial, or none.

In relying on a somewhat blindered and tautological view of VCD value, Ds have argued a proximate causation theory that considers the insureds' injury, which is <u>not</u> the prevailing view in Circuit Courts. Other cases Ds cite in their SJ Brief, Doc. No. 2562-1:41-42, are equally unsuccessful as these assume that TPPs feature as downstream injured parties in the chain of their insureds' causation. That is not at all the situation here, where TPPs have properly claimed and asserted facts relating to their direct injury, all of which revolve around Ds alleged non-compliance with cGMPs by which they placed allegedly unmerchantable drugs into the

[60] Defendants here rely on both *Sargeants* and *UFCW Local 1776*.

U.S. market.

In a case involving insurers' reimbursement for their insureds' medications, the Ninth Circuit posed the following question:

> "In civil actions brought under the Racketeer Influenced and Corrupt Organizations Act ("RICO") against pharmaceutical companies, do patients and health insurance companies who reimbursed patients adequately allege the required element of proximate cause where they allege that, but for the defendant's omitted mention of a drug's known safety risk, they would not have paid for the drug?"

Painters and Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Company Limited, 943 F.3d 1243 (9th Cir. 2019). This Court finds that, even though this MDL does not concern a RICO claim, the TPPs here are posing the same question.

In developing its answer, the Ninth Circuit derided the decisions in all three Second Circuit cases that Ds cited in their Omni SJ Brf:29-30 regarding "attenuated" proximate cause. The Ninth Circuit looked at how each of the First, Second, Third, and Seventh Circuits have answered that question and considered the very cases Ds cited in their SJ brief but refused to accept the Second Circuit's reasoning there. The *Painters* Court stated:

> "Indeed, it seems the central dispute between the Second and Seventh Circuits and the First and Third Circuits is whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP. We think the First and Third Circuits have it right because their reasoning is more consistent with the Supreme Court's direct relation requirement.
>
> [A]lthough prescribing physicians serve as ***intermediaries*** between Defendants' fraudulent omission of [the drug manufacturer] risk of causing bladder cancer and Plaintiffs' payments for [the drug], prescribing physicians do not constitute an *intervening cause* to cut off the chain of proximate cause. An intervening cause is "a later cause of independent origin that was not foreseeable." *Mendez v. County of Los Angeles*, 897 F.3d 1067, 1081 (9th Cir. 2018) (quoting *Exxon Co. v. Sofec*, 517 U.S. 830, 837, 116 S.Ct. 1813, 135 L.Ed.2d 113 (1996)). Here, since Actos was a *prescription* drug, it was *required* to be prescribed by physicians. Hence, it was perfectly foreseeable that physicians who *prescribed* Actos would play a causative role in Defendants' alleged fraudulent scheme to increase Actos's revenues. Further, "because of the structure of the American health care system," Defendants have always known

> that "physicians would not be the ones paying for the drugs they prescribed." [*In re*] *Neurontin [Marketing and Sales Practices Litigation*], 712 F.3d [21] ,at 38–39 [9th Cir. 2013]. Rather, they are well aware that TPPs and individual patients pay for the drugs. *See In re Avandia*, 804 F.3d [633] at 645 [3rd Cir. 2015]. Defendants' alleged fraudulent marketing scheme, which was intended to increase Actos's sales, "only became successful once [they] received payments for the additional [Actos] prescriptions [they] induced"—the very injury for which Plaintiffs seek recovery. *Neurontin*, 712 F.3d at 39. This is consistent with the Supreme Court's requirement that the proximate cause inquiry focus on the direct relation between the alleged violation and alleged injury. *Hemi Group [LLC v. City of New York, NY]*, 559 U.S. [1] at 12, 130 S.Ct. 983.
>
> **If we were to hold the opposite—that prescribing physicians' and pharmacy benefit managers' decisions constitute an intervening cause to sever the chain of proximate cause—as the Second and Seventh Circuits have held, drug manufacturers would be insulated from liability for their fraudulent marketing schemes, as they could continuously hide behind prescribing physicians and pharmacy benefit managers.** That is not the purpose the requirement *1258 of proximate cause is intended to serve. Proximate cause exists to 'limit a person's responsibility for the consequences of that person's own acts.' *Holmes [v. Securities Investor Protection Corporation]*, 503 U.S. [258] at 268, 112 S.Ct. 1311. Here, Plaintiffs seek to hold Defendants liable for the consequences of their own acts and omissions toward Plaintiffs: the money spent by Plaintiffs to purchase Actos."

Painters, 943 F.3d at 1257-1258 [emphasis added].

As the greater number of Circuit Courts have found proximate cause to be an unsuccessful and legally inappropriate argument in disputes where insurers seek direct damages from drug manufacturers, and especially as *Blue Cross Blue Shield* in this Circuit has already ruled on the very same issues as here, this Court finds no legal support for Ds request for summary judgment under their proximate cause theory of damages.

Accordingly, on the issue that plaintiffs cannot prove that defendants' alleged conduct or misrepresentations proximately caused injury to TPPs, the Court **DENIES** Ds Omnibus summary judgment motion (Doc. No. 2562). Further, the Court **PROHIBITS** defendants from raising to the fact-finder that intervening or distant or attenuated causes of TPPs injury exist because physicians function as intermediaries in the U.S. drug supply chain or because of insureds' pre-existing medical conditions or variability in insureds' dosages or ingestion

duration.

9.4 That Plaintiffs Cannot Prove Fraud or Warranty Based Damages

In their SJ Brf. (Doc. No. 2562-1), Ds aver that the TPPs cannot prove fraud or warranty damages because in pharmaceutical cases, when drugs function as intended, the TPPs have received proper benefit of the bargain, which corresponds to TPPs payment for the VCDs. Ds declare Ps have neither argued nor shown that the VCDs did not work as intended. Also, since TPPs are not the consumers who actually received the benefit of hypertension relief, TPPs themselves cannot assert they did not get what they paid for in the reimbursed VCDs. Since TPPs cannot assert they suffered injury, Ds argue the TPPs can prove no ascertainable loss for their reimbursements of their insureds' VCDs.

The Court finds the cases Ds cite in this section are inapposite, in particular *Heindel v. Pfizer Inc.*, 381 F.Supp. 23 (D.N.J. 2004). The *Heindel* court states the gravamen as:

> "Plaintiffs in this matter are t**wo consumers** who suffer from pain associated with osteoarthritis and other conditions. Both took prescription drugs to treat their conditions and both got relief from the drugs they took. Though neither plaintiff suffered any physical injury from either of the drugs at issue, both now claim that they are entitled to damages for the "economic injuries" they suffered **due to Defendants' failure to publicize the results of two clinical studies** that revealed possible risks associated with the use of the drugs." *Id*. at 366.

Heindel as well as *In re Rezulin,* 210 F.R.D. 61, 68 (S.D.N.Y.2002),[61] upon which *Heindel*

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[61] Which is a class certification decision regarding a drug that was NOT contaminated by the API mfr but which caused contra-indications leading to serious biological harm.

The Court states again as it has in other opinions that *Rezulin* is not apposite here. This MDL, as opposed to the *Rezulin* MDL, concerns breach of warranty and fraud claims NOT because ZHP hid unfavorable or dangerous results and testing evidence from the FDA of contraindications that eventually amounted to dangerousness, the core complaint in the *Rezulin* MDL.

Rather, this MDL concerns allegedly affirmative manufacturing conduct by the drug API mfr that resulted in nitrosamine-contaminated drugs that were sold in the U.S. market. ZHP affirmatively changed its manufacturing process, conduct over which it had total and complete control, and which affirmatively introduced into the API a genotoxic carcinogen known for 50 years to be a probable human carcinogen.

The non-disclosure of unfavorable or even dangerous test data to the FDA could have demonstrated fraud were facts shown of Lambert-Warner's intent to conceal that data COUPLED WITH A GENERAL BODY OF SCIENTIFIC LITERATURE pointing to causation between the *Rezulin* drug and the injuries complained of.

Since the Rezulin injury—whether products liability or economic—was not rooted in a general scientific understanding about *Rezulin* as the cause, that Court found there could only be individualized inquiry about each consumer's injury. But that is not the situation here. Here, there can be evidence adduced from general chemical principles about how the genotoxic carcinogen entered the API.

In the TPP trial, which concerns economic loss liability of TPP insurers, there seems a small, if any, need for inquiry into individual facts of consumers' ingestion of VCDs so to answer whether a consumer or a class could, do, will, or may have a heightened risk of cancer development. Ps seek to present evidence to the fact-finder as to what the defendants should have

relies and Ds much tout, stand for the proposition that there can be NO economic injury when the consumer who ingested the drug got the benefits of the bargain, that is, by receiving the medical treatment that the ingested drug was supposed to deliver. *Heindel* and *Rezulin* are about contraindications in taking their respective drugs. They do not concern drug mfrs selling drugs they contaminated with nitrosamines, probable genotoxic carcinogens, because of their allegedly affirmative misrepresentations that the drugs had been made and quality controlled in a way that warranted their safety and purity.

Ds argument arises from their assumptions about their liability: there can be no warranty breach or fraud because TPPs got the benefit of the bargain by paying for VCDs that lowered their insureds' blood pressure and because Ds did not act with scienter in making and selling nitrosamine-contaminated drugs. Ds liability argument is contra positioned to Ps argument that the TPPs paid for worthless VCDs because of the nitrosamine contamination caused by Ds affirmative conduct not to make or sell safe drugs. Had the FDA known of the nitrosamine contamination before June 2018, the VCDs would not have been sold. Moreover, the economic loss due to warranty breach and fraud were not due to an allegedly, inadequate labelling or undisclosed safety risk as in *Heindel* and *Rezulin* but to a *bona fide* risk identified by the FDA (and other health regulatory agencies) of an increased probability of cancer development. The Court sees that Ds liability assumption of therapeutic efficacy does not resolve the issue or demonstrate no genuine dispute of material fact. The Court finds Ds assumptions gird its liability theory but do not address the full story of what the fact-finder must resolve.

Put simply, whether Ds breached express warranties, and misrepresented the safety of their VCDs by putting them on the market without adequate safety/quality testing and/or are liable for fraud requires the fact-finder to determine material facts that are genuinely and intensely disputed here. In particular, such determination involves a weighing of the efficacy of the VCDs in lowering blood pressure vs. Ds alleged conduct in not complying with cGMPs, compendial standards; Ds own purported suspicions about the contamination, and Ds allegedly inadequate quality measures to test the degradation products of their changed manufacturing processes. Such fundamental averments genuinely disputed do not and cannot support a grant of summary judgment.

Moreover, the Court adds that, while lowering consumers' blood pressure, the VCDS also increased consumers' likelihood of developing cancer, especially of liver, lung, and stomach, to about 1 chance in every 8000 VCD consumers taking the highest dose of the

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done to prevent or discover the contamination. And as an answer to that question, individualized facts about individual consumers' causation liability are of little direct relevance.

medication over a period of four years. Such a probability the Court finds is more than a contra-indication, which is why *Heindel* and *In re Rezulin* are not on point. As the biological effects of the VCDs are Janus-faced, the Court finds support to have the fact-finder decide whether TPPs did or not get the benefit of the bargain.

Accordingly, on the issue that plaintiffs cannot prove fraud and breach of warranty damages, the Court **DENIES** defendants' Omnibus motion for summary judgment (Doc. No. 2562). For clarity, the Court has not ruled that Ps have proved fraud and breach of warranty damages, but is ruling that Ps are entitled to put before the fact-finder evidence that, Ps aver, proves such damages.

9.5 That Plaintiffs Cannot Prove Punitive Damages

Ds point out that in order to justify an award of punitive damages, a choice of law analysis is a preliminary prerequisite to resolving where Ps may seek punitive damages for their claims. The Court agrees with both parties' arguments that the choice of law analysis is more strongly decided not in favor of New Jersey but for the jurisdiction where the TPP is located and presumably paid for the VCDs.

Moreover, the parties in their respective SJ briefs have alerted the Court to restrictions in some jurisdictions for certain claims. Combining the parties' research and arguments, the Court finds that the listed jurisdictions below permit punitive damages as a remedy for a breach of express warranty, fraud, or violation of state consumer protection laws.

As for Nebraska and New Hampshire, Ds point out that regardless of legal claim, these states do NOT permit an award of punitive damages. The Court agrees.

Moreover, Ds assert some jurisdictions require more stringently demonstrated elements for fraud and consumer protection laws than plaintiffs have offered evidence for. These elements include a demonstrated egregiousness of Ds fraudulent conduct and maliciousness well beyond an intent to deceive, which Ds argue the evidence cannot show. Since Ps cannot meet these heightened standards, Ds seek summary judgment on punitive damages in all jurisdictions in the fraud and consumer protections subclasses.

Other than for Nebraska and New Hampshire, Ds also cite caselaw for North Carolina that prohibits recovery of punitive damages for fraud. Further, Ds also cite caselaw in Ohio, New York, and Louisiana, which they argue demonstrate heightened standards of proof. The Court has reviewed Ds cited cases and finds for the most part Ds have given an incomplete view of the standards regarding punitive damages in those states. As it turns out, none of these four states—North Carolina, Ohio, New York and Louisiana— prohibits punitive damages for

fraud claims. *See* fn. 62.[62]

Based on facts to be presented to the fact-finder, Ps argue their evidence satisfies the standards—heightened or otherwise—for punitive damages in all subclasses. To support their assertion, Ps list case law citations, which the Court does not find incorrect. *See* Ps Opp. Brf.

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[62] The Court agrees Ohio has a fraud-plus-more pleading standard in order to justify an award of punitive damages. However, Ds quotation to *K. Ronald Bailey & Assocs. Co. v. Soltesz,* No. E-05-077, 2006 WL 1364019 (Ohio Ct. App. 19 May 2006) by no means clarifies what that is. The *Bailey* Court stated:

> " Punitive damages may be awarded in a fraud case where, in addition to the elements of fraud, a party proves: 'that the fraud was aggravated by the existence of malice or ill will, or must demonstrate that the wrongdoing was particularly gross or egregious.' [citation omitted]... Malice may be defined in two ways: ... (2) extremely reckless behavior revealing a conscious disregard for a great and obvious harm." *Id.* at *3.

"Aggravated fraud" evidence is what Ps purport to show by eliciting facts and arguing in their SJ brief that all Ds were extremely reckless in their non-compliance with cGMPs and in particular, by not testing the chemical results of ZHPs changed manufacturing processes or by relying, without more, on ZHP assurances of quality.

As for Ds citation of North Carolina law that punitive damages are not recoverable for fraud, that is incorrect. The North Carolina Supreme Court expressly stated in *Newton v. Standard Fire Ins. Co.*, 291 N.C. 105 (1976):

> "The aggravated conduct which supports an award for punitive damages when an identifiable tort is alleged may be established by allegations of behavior extrinsic to the tort itself, as in slander cases. [citations omitted]. **Or it may be established by allegations sufficient to allege a tort where that tort, by its very nature, encompasses any of the elements of aggravation. Such a tort is fraud**, since fraud is, itself, one of the elements of aggravation which will permit punitive damages to be awarded. *See Saberton v. Greenwald* [146 Ohio St. 414 (Sup.Ct. of Ohio 1946)] *supra*, which allowed punitive damages for a fraudulent representation that induced the plaintiff to buy an old watch in a new case." *Newton*, 291 N.C. at 112-113. [emphasis added].

As for Ds assertion that Louisiana case law prohibits recovery of punitive damages in an action for fraud, again not correct. In particular, *Warren v. Shelter Mut. Ins. Co.*, 196 So.3d 776 (Ct. of App. of La., Third Circuit 2016) concerned a products liability case involving a defective motor boat engine, which the manufacturer knew of and kept it undisclosed. The *Warren* plaintiff sought a punitive damages award for the boat manufacturer's fraud. The W*arren* court reviewed various state law punitive damages awards for their fit with U.S. Supreme Court guidance and 14th Amendment due process considerations and affirmed the jury's exceptionally large punitive damages award in a maritime case:

> "For all of the reasons expressed above, we find that the punitive damages awarded by the jury in this case do not violate constitutional due process under the guideposts articulated in *BMW [of North America, Inc. v. Gore,* 517 U.S. 559 (1996) nor are they excessive under the reasoning of *Exxon [Shipping Co. v. Baker,* 554 U.S. 471 (2008)]. Accordingly, we affirm the judgments of the trial court in all respects on the issues raised in appeal number 15–1113." *Warren*, 196 So.3d at 817.

Warren concerned the excessiveness of punitive damages for fraud awarded by a Louisiana jury. Clearly such damages are not disallowed in products liability cases in Louisiana. Further, there is no negative treatment for this case.

See also, Warren v. Shelter Mutual Insurance Company, 233 So.3d 568, 596 (Sup. Ct. of La. 2017) where, on Ds appeal of the large punitive damages award, the Louisiana Supreme Court agreed that, although the boat manufacturer's conduct was reprehensible, and certainly within the punishable spectrum, the evidence did not support characterizing the boat manufacturer's conduct as on the extreme end of malicious behavior and dangerous activity, and carried out for the purpose of increasing a tortfeasor's financial gain. Consequently, the Louisiana Supreme Court found the $23,000,000 punitive damages award higher than reasonably required **to satisfy the objective of punitive damages awards**: punishment, general deterrence, and specific deterrence.

The *Warren* cases are dispositve that punitive damages are not only allowed for Louisiana products liability actions but that under Louisiana law there are "standard" vs. "egregious" punitive damages, distinguished by a fact intensive review of the quality of defendant's maliciousness.

Ds citation to New York standards regarding punitive damages for fraud is accurate; the weightiest citation for this issue under New York jurisprudence is *Walker v. Sheldon*, 10 N.Y.2d 401, 405 (1961). In their Omni SJ brief, Ds imply that New York's fraud standards also applied to Ohio, North Carolina, and Louisiana, which is an unfortunate assertion for its inaccuracy.

Doc. No. 2606-1:45-49, n. 42-43.

Based on the parties' arguments, the Court finds:

The **Breach of Express Warranty Subclass Group b** includes these jurisdictions: Alabama, Arkansas, Florida, Georgia, Mississippi, Montana, ~~**Nebraska**~~, Nevada, ~~**New Hampshire**~~, New York, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin, and Wyoming, with **Nebraska and New Hampshire being excluded**;

The **Common Law Fraud Subclass Group c** includes those jurisdictions where the scienter standard is the highest: Alaska, Arkansas, Colorado, District of Columbia, Florida, Idaho, Iowa, **Louisiana**, Massachusetts, Minnesota, New Jersey, **New York, North Carolina**, North Dakota, **Ohio**, Oklahoma, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wyoming, and Puerto Rico, with the bolded jurisdictions in the Fraud Subclass expressly retained;

The **Consumer Protection Laws Subclass Group a** includes those states where no showing of intent is required to prove deception: Alaska, Arizona, California, Connecticut, Florida, Louisiana, Missouri, ~~**Nebraska, New Hampshire**~~, New York, North Carolina, North Dakota, Oklahoma, Pennsylvania, and Washington, with **Nebraska and New Hampshire being excluded.**

For clarity, Ps Omnibus motion for summary judgment (Doc. No. 2569) for breach of express warranty and violation of consumer protection laws does not seek punitive damages. Nor do Ps individual motions for summary judgment against ZHP (SJ Brf., Doc. No. 2569-2) or Torrent (SJ Brf., Doc. No.2559-1) seek punitive damages for fraud. Ps aver damages will be shown at trial. For that reason, the Court finds that Ds arguments and asserted facts regarding punitive damage as well as Ps SOMFs and opposition SOMFs demonstrate a genuine dispute of material facts on the issues of punitive damages and proof of scienter and leaves these issues for the fact-finder.

Accordingly, on the issue that plaintiffs cannot prove punitive damages, the Court **DENIES** defendants' Omnibus motion for summary judgment (Doc. No. 2562);

EXCEPT, the Court **GRANTS** defendants' Omnibus motion for summary judgment (Doc. No. 2562) on the issue of seeking punitive damages on for breach of express warranty, and violation of state consumer protection laws in **Nebraska and New Hampshire**.

9.6 Resolution of Defendants Omnibus Motion for Summary Judgment on Damages

Summarizing section 9.0, the Court **DENIES** defendants' Omnibus motion for summary

judgment (Doc. No. 2562) on the following issues relating to TPPs damages:

9.1: That plaintiffs have no cognizable injury because the disparity between parties' theories of liability raises a genuine dispute of material facts for resolution by the fact-finder,

9.2: That plaintiffs' model of damages cannot establish damages on a class-wide basis because of the mismatch between how the TPP subclasses were defined versus the basis of TPPs standing.

That plaintiffs' model of damages calculates TPP damages on a Point of Sale basis rather than on a Point of Payment basis, i.e., using TPPs home jurisdictions, which is not fatal because the parties may apply a translating mechanism, recognized in Third Circuit cases, that converts TPP POS jurisdictions into TPP POP jurisdictions and calculate TPP damages for POP jurisdictions.

9.3: That plaintiffs cannot prove that defendants alleged misrepresentations and fraudulent conduct proximately caused any injury. As the greater number of Circuit Courts have found proximate cause to be unavailing in disputes where insurers directly seek damages from drug manufacturers, Ds proximate cause theory of economic loss damages lacks legal support.

9.4: That plaintiffs' fraud or breach of express warranty damages cannot be proved. Damages for fraud and express warranty claims require the fact-finder to resolve material facts genuinely and intensely disputed here, including whether defendants had enhanced or lessened malice in not testing or conducting risk assessments regarding the unqualified changes in VCD manufacturing processes.

9.5: That plaintiffs cannot prove punitive damages because plaintiffs have not cited incorrect case law in jurisdictions requiring heightened pleading of malice for fraud, **EXCEPT THAT**: defendants have shown that **Nebraska and New Hampshire** prohibit punitive damages for the breach of express warranty claim and violation of consumer protection laws.

10.0 CONCLUSION

1) On the claim of breach of implied warranty, the Court **GRANTS**:

defendants' Omnibus summary motion for judgment (Doc. No. 2562).

2) On the issue whether defendants' affirmations, statements, labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the Orange Book formulation, the Court **GRANTS**:

plaintiffs' Omnibus motion for summary judgment (Doc. 2569);

and **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. 2562).

3) On the issue whether the VCDs sold before the recalls began in July 2018 were adulterated, The Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569);

defendants' Omnibus summary motion for judgment (Doc. No. 2562);

ZHP's, Teva's, and Torrent's individual motions for summary judgment (Docs. No. 2564, 2565, and 2570, respectively).

4) On the issue whether defendants violated cGMPs and compendial standards in making nitrosamine-contaminated API and FD VCDs and in marketing and selling them before the recalls began in July 2018, The Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569); and

defendants' Omnibus summary motion for judgment (Doc. No. 2562).

5) On the issue whether defendants breached express warranties to plaintiffs in TPL Express Warranty Subclass b, the Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569); and

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

6) On the issue whether plaintiffs have given defendants pre-suit notice of the breach of express warranty claim,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562);

and **GRANTS**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569).

7) On the issue whether the statute of limitations limits the filing of breach of express warranty claims in some jurisdictions in TPP Express Warranty Subclass b,

the Court **DENIES**:

Ds Omnibus motion for summary judgment (Doc. No. 2562):

and **GRANTS**:

Ps motion for summary judgment (Doc. 2569).

8) On the issue whether tolling of the statute of limitations for the express warranty claim may be justified in some or all jurisdictions in the TPP Express Warranty Subclass b,

the Court **DENIES**:

plaintiff's Omnibus motion for summary judgment (Doc. No. 2569); and

defendants Omnibus motion for summary judgment (Doc. No. 2562).

9) On the issue whether plaintiffs relied on defendants' express warranties, the Court **DENIES**:

plaintiff's Omnibus motion for summary judgment (Doc. No. 2569); and

defendants Omnibus motion for summary judgment (Doc. No. 2562).

10) On the issue of violation of Consumer Protection Statutes,

the Court **DENIES**:

plaintiffs' Omnibus motion for summary judgment (Doc. No. 2569);

defendants' Omnibus motion (Doc. 2562); and

Teva's motion for summary judgment (Doc. No. 2565),

EXCEPT the Court **GRANTS:**

defendants' Omnibus motion (Doc. 2562) and Teva's motion (Doc. No. 2565) for these claims in Missouri.

11) On the issue of fraud , the Court **DENIES**:

plaintiffs' motion for summary judgment against ZHP (Doc. No. 2569); and

plaintiffs' motion for summary judgment against Torrent (Doc. No. 2559).

defendants' Omnibus motion for summary judgment (Doc. No. 2562);

defendant ZHP's motion for summary judgment (Doc. No. 2564);

defendant Teva's motion for summary judgment (Doc. No. 2565);and

defendant Torrent's motion for summary judgment (Doc. No. 2570).

12) On the damages issue whether plaintiffs have no cognizable injury,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

13) On the damages issue whether plaintiffs' model of damages cannot establish damages on a class-wide basis,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

14) On the damages issue whether plaintiffs cannot prove defendants' alleged conduct and/or misrepresentations proximately caused plaintiffs any injury,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

15) On the damages issue whether plaintiffs cannot prove fraud and breach of warranty damages,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562).

16) On the damages issue whether plaintiffs cannot prove punitive damages,

the Court **DENIES**:

defendants' Omnibus motion for summary judgment (Doc. No. 2562),

EXCEPT the Court **GRANTS**:

defendant's Omnibus summary judgment motion (Doc. No. 2562) on the issue that plaintiffs cannot prove punitive damages in Nebraska and New Hampshire, for breach of express warranty and for violation of Consumer Protection Laws.

Dated: 26 March 2024

s/ Robert B. Kugler
Honorable Robert B. Kugler
United States District Judge